PREDICTING FACTORS & CLINICAL OUTCOMES OF FEMOROPOPLITEAL ANGIOGRAPHIC DISSECTION FOLLOWING BALLOON ANGIOPLASTY

By

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Reg. No. 333-27112-202-231683

Dissertation submitted to the National Board of Examinations, New Delhi.

In partial fulfilment of the requirements for the degree of

DOCTORATE OF NATIONAL BOARD IN

VASCULAR SURGERY

Under the guidance of

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2020-2023

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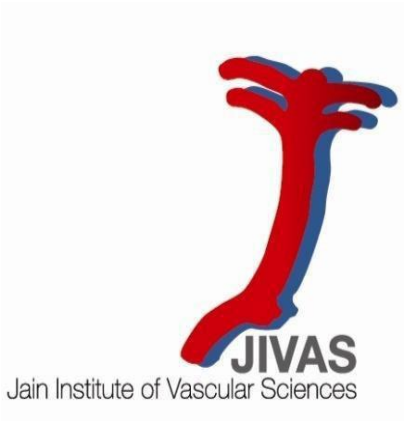

AUGUST 2023

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DECLARATION CUM UNDERATKING FOR FRESH THESIS

I, Dr. Siddharth M hereby declare that this thesis entitled "**PREDICTING FACTORS & CLINICAL OUTCOMES OF FEMOROPOPLITEAL ANGIOGRAPHIC DISSECTION FOLLOWING BALLOON ANGIOPLASTY**" is 'bonafide' in nature and was carried out by me under the guidance and supervision of Dr. Sumanth Raj KB. The interpretations put forth are based on my reading and understanding of the original texts and they are not published anywhere in the form of books, monographs or articles. The other books, articles and websites, which I have made use of are acknowledged at the respective place in the text. For the present thesis, which I am submitting to the National Board of Examinations, New Delhi, no degree or diploma or distinction has been conferred on me before elsewhere.

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I hereby declare that this dissertation titled "**PREDICTING FACTORS & CLINICAL OUTCOMES OF FEMOROPOPLITEAL ANGIOGRAPHIC DISSECTION FOLLOWING BALLOON ANGIOPLASTY**" is a bonafide and genuine research work carried out by me under the guidance and supervision of **Dr. Sumanth Raj**, Consultant Vascular surgeon, Jain Institute of Vascular Sciences (JIVAS), Bhagwan Mahaveer Jain Hospital, Bengaluru, in partial fulfilment of the requirement of National Board of Examinations regulation for the award of the Degree of DrNB in Peripheral Vascular Surgery.

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ACKNOWLEDGEMENTS

During this journey of the compilation of my thesis, I have been helped, supported and encouraged by many, and I am feeling short of words to express my gratitude towards them.

I consider myself lucky to have ***Dr. Sumanth Raj, Consultant Vascular Surgeon****, Jain Institute of Vascular Sciences (JIVAS), as my supervisor and mentor. He has been a great teacher and a splendid personality. His clinical acumen, surgical skill and wisdom are well known and unparalleled. I will always cherish the time I spent under his guidance. He is, and will always remain as a source of inspiration for me.*

I am extremely thankful to ***Dr. K.R. Suresh,*** *Director, JIVAS for his helping attitude and invaluable guidance that has helped me bring this work to its logical conclusion.*

I express my sincere thanks to ***Dr. Vivekanand, Dr. Vishnu M, Dr. Girija, Dr. Nikil, Dr. Mamatha S H*** *and* ***Dr. Indushekar Consultants****, JIVAS for their valuable help and the encouragement and support they provided me, during my work.*

I sincerely thank all the patients who were part of the study for their cooperation.

I express my gratitude for the generous help and cooperation provided to me by my seniors ***Dr. Nishan, Dr. Siva Krishna, Dr. Vishal, Dr. Ahsan V P Dr. Surya Kiran, Dr. Pavan B K*** *and my colleagues* ***Dr. Pranjal M. and Dr. (Lt Col) Vinay Nazareth, my juniors Dr. Ishita, Dr. Siju, Dr. Vijay, Dr. Abhilash and Dr. Ashik*** *in completing my work. I would like to express my gratitude to* ***Dr. Chandrashekar M*** *for his important contribution in teaching me the usage of SPSS and statistics.*

I would like to express my gratitude to ***Dr, Chethana & Dr. Poonam*** *for data collection.*

I would like to express my gratitude to all our department staff Mrs. Hema, Mrs. Deepa, Mr. Sunil, Mr. Ashok, Mr. Uday, Mr. Albert, Mrs. Prema,Mr.Venky for their help in maintaining patient records and for data collection.

I am very grateful to my family for their relentless love and affection towards me.

Last but not the least; I specially thank my Wife ***Dr. Sneha Karanth*** *for her constant support and cooperation*

To my darling Ishanvi, I give you all my love and my thanks for bearing with and understanding my absence due to the requirements of the Course.

Place: Bengaluru

August 2023

TABLE OF ABBREVIATIONS AND ACRONYMS:

ABI	Ankle brachial index
AI	Aortoiliac
AKA	Above knee amputation
AP	Ankle pressure
AT	Anterior tibial
BKA	Below knee amputation
BMI	Body mass index
CAD	Coronary artery disease
CFA	Common femoral artery
CKD	Chronic kidney disease
CLI	Critical limb ischemia
CLTI	Chronic limb threatening ischemia
CT	Computed tomography
CTA	Computed tomography angiography
CTO	Chronic total occlusion
CVD	Cerebro vascular disease
DAPT	Dual antiplatelet therapy
DCB	Drug coated balloon
DES	Drug eluting stent
DFU	Diabetic foot ulcer
DM	Diabetes mellitus
DP	Dorsalis pedis
DSA	Digital subtraction angiography
DUS	Duplex ultrasound
FP	Femoropopliteal
GLASS	Global Limb Anatomic Staging System
GVG	Global Vascular Guidelines

IC	Intermittent claudication
IM	Inframalleolar
IP	Infrapopliteal
LDL	Low density lipoprotein cholesterol
MACE	Major adverse cardiovascular event
MALE	Major adverse limb event
MRA	Magnetic resonance angiography
PAD	Peripheral artery disease
PBA	Plain balloon angioplasty
PFA	Profunda femoris artery
PSV	Peak systolic velocity
PSVR	Peak systolic velocity Ratio
PVR	Pulse volume recording
RCT	Randomized controlled trial
SFA	Superficial femoral artery
SVS	Society for Vascular Surgery
TBI	Toe brachial index
TcPO2	Transcutaneous oximetry
WFVS	World Federation of Vascular Societies
WIfI	Wound, Ischemia, foot Infection

ABSTRACT

TITLE: Predicting factors & clinical outcomes of Femoropopliteal angiographic dissection following balloon angioplasty

Aim

- To investigate the predicting factors & clinical outcomes of femoropopliteal angiographic dissection following balloon angioplasty.

Objectives

1. To study the clinical outcome in different femoropopliteal angiographic dissection pattern
2. To study the predictive factors for severe femoropopliteal dissection types
3. To study the effect of balloon inflation time on femoropopliteal angiographic dissection
4. Type of Balloon [long vs short] associated with angiographic dissection

MATERIALS and METHODS:

Prospective, institution based observational study

- Patients treated for femoropopliteal angioplasty was included in the period between April 2021 to march 2022
- Vessel dissection after the initial balloon angioplasty procedure will be graded into 3 types based on the circumference involvement

RESULTS: The main findings of this study are the PSVR in the mild angiographic dissection group was similar to that in the moderate dissection group. The PSVR in the mild and moderate angiographic dissection group was significantly worse compared with that in the no dissection group, which is in corelation to study done by Norihiro Kobayashi et al[30]. The distribution of Above ankle amputation is significantly different depending on type of dissection ($p = 0.035$) with a greater number of amputations with increasing grade of dissection. The distribution of Death is not significantly different depending on type of dissection ($p = 0.55$). The distribution of Post 6m WIfI stage is significantly different depending on type of dissection ($p = <0.01$) with a greater number of patients in stage 4 in type 2 dissection group.

CONCLUSION:

- There is a significant difference in PSVR , WIfI stage at 6th month follow up & above ankle amputation in patients of femoropopliteal non flow limiting dissection based on simple classification for angiographic dissection, with higher PSVR ,WIfI stage, above ankle amputation with increasing grade of dissection.
- There are no significant predicting factors for different types of femoropopliteal dissection in my study
- Balloon inflation time and balloon lengths had no effect of type of angiographic dissection in femoropopliteal segment

CONTENTS

Introduction:

In comparison to traditional balloon angioplasty, the use of bare-metal and drug-eluting stents has increased the primary patency rate for femoropopliteal lesions. [1,2] Restenosis, stent thrombosis, and stent fracture, however, limit their long-term endurance. [3,4] The focus has shifted more and more to a stent-free approach for treating femoropopliteal lesions and the significance of atherectomy devices for lesion reduction. [5] and drug-coated balloons (DCBs) have recently been shown to have a clinical impact. For femoropopliteal lesions, balloon angioplasty is still a common form of endovascular therapy (EVT). Dissection following balloon angioplasty is one of the issues with this approach, though. [6,7]

It has been demonstrated that the severity of angiographic dissection in coronary artery disease is correlated with worse clinical outcomes. [8,9] However, categorization of angiographic dissection for femoropopliteal lesions is still not a practice that is universally supported. Furthermore, there are many different forms of angiographic dissection following balloon angioplasty for femoropopliteal lesions, making it challenging to match the classification of coronary artery disease as it is for those lesions. Therefore, the severity of angiographic dissection for femoropopliteal lesions was assessed on the basis of its clinical impact, based on a simpler classification established by Norihiro Kobayashi et al [21].

Review of literature:

The likelihood of developing peripheral arterial disease (PAD) drastically rises with advancing age.[10] The onset of an aging society is currently a problem for developed and developing nations, and one of the new clinical difficulties is the rising prevalence of PAD. In the last ten years, PAD has grown.[11]

Endovascular therapy (EVT) for femoropopliteal (FP) lesions has undergone technological advancements to keep up with the exponential rise in EVT cases, but the patency rate of EVT for FP lesions has not been reported to be favourable compared with bypass surgery using a vein graft.[4] The nitinol stent has been reported to have a satisfactory result when compared to angioplasty alone for addressing the problem areas in EVT.[14]

Recently, reports have also been made on the effectiveness of a drug-eluting stent called Zilver PTX (Cook Medical, Bloomington, Indiana).[15] Understanding existing EVT problems as well as technological advancements will be crucial for enhancing EVT results in the future. In other words, we could enhance the results of EVT by comprehending and overcoming its current weaknesses.

Endovascular therapy (EVT), whose use has been growing as a result of an aging population and improved peripheral vascular disease diagnostics, is now universally acknowledged as a successful treatment for symptomatic superficial femoral artery (SFA) and popliteal artery disease.[11]

Compared to traditional balloon angioplasty, including bailout stent-assisted balloon angioplasty, [12] In-stent restenosis (ISR) nevertheless continues to be a significant disadvantage of stent-based therapies, despite the widespread use of nitinol stents. Nitinol stents are mostly linked to the risk of thrombosis and fracture.[14]

The "nothing left behind" strategy has been promoted ever since drug-coated balloons (DCB) and different atherectomy devices were approved. This refers to making nitinol stents as compact and brief as possible. Furthermore, two randomized controlled trials indicated that primary nitinol stent implantation was equivalent to optimal balloon angioplasty without bailout stent implantation in terms of clinical outcomes.[15] However, balloon angioplasty frequently causes flow-limiting dissection and/or insufficient arterial dilation.

The National Heart, Lung, and Blood Institute categorization system of coronary artery dissection types is proposed in the field of coronary artery disease to predict results after balloon angioplasty.[17] However, due to the bigger vessel diameter and longer lesion length, femoropopliteal lesions have a higher plaque burden than coronary artery disease.

The National Heart, Lung, and Blood Institute classification system cannot be easily applied for femoropopliteal lesions due to the numerous dissection variations that may manifest in the treated lesion. However, both in coronary artery

disease and femoropopliteal lesions, extensive angiographic dissection is linked to worse clinical results following balloon angioplasty.

In the realm of EVT for femoropopliteal lesions, the idea of "leaving nothing behind" has recently been put up because the clinical outcomes following stent insertion are unsatisfactory and the technology of DCBs and atherectomy devices has evolved.[24]

In comparison to conventional balloon angioplasty, DCBs dramatically increased the primary patency rate for relatively uncomplicated lesions, according to the IN.PACT superficial femoral artery trial's encouraging findings (78.9% vs. 50.1%; P.001). 15 Furthermore, Schmidt et al. showed that a DCB works well for complicated femoropopliteal injuries.[23] Long lesions and severe calcification are recognized as predictors of restenosis after balloon angioplasty with DCB, despite the abundance of data supporting DCB that has surfaced.[23]

Before balloon angioplasty for these lesions, plaque reduction and lesion modification are critical methods to reduce the risk of dissection and create a broad lumen region.[21]

Additionally, according to Dattilo et al's research, [26], balloon angioplasty is inferior to orbital atherectomy plus balloon angioplasty in terms of dissection rate (15.8% vs. 48.1%; P 14.02), post mean lumen diameter (4.6 6 1.0 vs. 3.3 6 1.3;

P.001), and freedom from target lesion revascularization or restenosis at 6 months (77.1% vs.

These investigations have demonstrated that atherectomy devices can lessen the formation of dissections and cover the area where balloon angioplasty with DCB is vulnerable. The severity of angiographic dissection for femoropopliteal lesions was assessed on the basis of a more straightforward classification proposed by Norihiro Kobayashi et al. [31] based on its clinical influence on future restenosis.

Classification of angiographic dissection after balloon angioplasty for femoropopliteal disease. Norihiro Kobayashi et al [21]

- Group A no angiographic dissection.
- Group B the width of the dissection was less than one-third of the lumen.
- Group C the width of the dissection was more than one-third of the lumen.

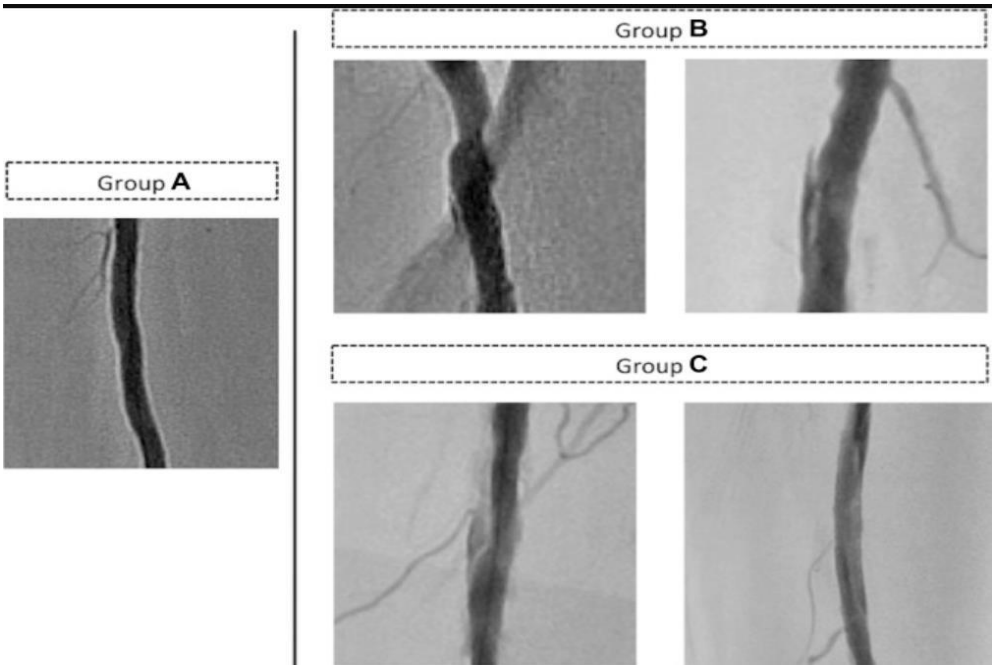

Figure 1 classification of angiographic dissection

Femoropopliteal (FP) disease grading in Global Limb Anatomic Staging System (GLASS). GVG guidelines

FP Grade 0	• Mild or no significant (<50%) disease
FP Grade 1	• Total length SFA disease <1/3 (<10 cm) • May include single focal CTO (< 5 cm) as long as not flush occlusion • Popliteal artery with mild or no significant disease
FP Grade 2	• Total length SFA disease 1/3-2/3 (10-20 cm) • May include CTO totalling < 1/3 (10 cm) but not flush occlusion • Focal popliteal artery stenoses <2 cm, not involving trifurcation
FP Grade 3	• Total length SFA disease >2/3 (>20 cm) length • May include any flush occlusion <20 cm or non-flush CTO 10-20 cm long • Short popliteal stenosis 2-5 cm, not involving trifurcation
FP Grade 4	• Total length SFA occlusion > 20 cm • Popliteal disease >5 cm or extending into trifurcation • Any popliteal CTO

Table 1 femoropopliteal disease gradin

Predicting factors & clinical outcomes of Femoropopliteal angiographic dissection following balloon angioplasty: An Institutional based prospective study

Aim

- To investigate the predicting factors & clinical outcomes of femoropopliteal angiographic dissection following balloon angioplasty.

Objectives

1. To study the clinical outcome in different femoropopliteal angiographic dissection pattern
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4. Type of Balloon [long vs short] associated with angiographic dissection

Material and Methods.

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- Patients treated for femoropopliteal angioplasty was included in the period between April 2021 to march 2022
- Vessel dissection after the initial balloon angioplasty procedure will be graded into 3 types based on the circumference involvement
- Group A: no angiographic dissection.
- Group B: the width of the dissection was < 1/3 rd. of the lumen.
- Group C: the width of the dissection was >1/3 rd. of the lumen.

Sample size calculation:

Sample Size	
Total	**48**
Study Parameters	
Incidence, group 1	10%
Incidence, group 2	45%
Alpha	0.05
Beta	0.2
Power	0.8

Table 2Sample size calculation:

Inclusion criteria

- Single or sequential de novo lesions (≥50% diameter stenosis or occlusion) in an Femoropopliteal segment
- Symptomatic [rest pain, tissue loss]

Exclusion criteria

- Patients treated with primary/selective/bailout stenting
- Technical failure resulting in non-completion of procedure

Intervention procedure:

Vascular access is achieved through the contralateral (crossover) or ipsilateral (antegrade) approach, at the operator's discretion, using a standard 6F or 7F sheath. After insertion of the sheath, an intra-arterial bolus of 5000 units of heparin was routinely administered. Baseline arteriography was also performed subsequently to assess the following variables: type of lesion (stenosis or occlusion); lesion location determined by means of a radiopaque ruler placed below the patient's upper thigh and measured. The reference vessel diameter was measured at the proximal vessel because the vessel diameter could be reduced distally to the lesions. A 0.035-inch, 0.018-inch, or 0.014-inch guidewire was used to cross the lesion. After passing the wire, balloon angioplasty was performed. All lesions were dilated with an optimally sized balloon based on the reference vessel diameter. We generally select an undersized balloon catheter compared with the reference vessel diameter. The selection of the balloon catheter was made at the operator's discretion. At our institution, we generally consider longer balloons for tandem lesions instead of multiple short balloons. Although the inflation pressure and duration were also at the operator's discretion, in cases of flow-limiting dissection or residual stenosis >30%, prolonged balloon dilation that was 1 to 2 minutes longer than the initial dilation was performed, mostly based on the RBP and standard inflation time. Bailout stent implantation was performed when flow-limiting dissection and recoil could not be resolved even after prolonged balloon dilation by angiographic assessment, according to the operator's discretion. However, if stenting was finally performed, these lesions were excluded from the study.

Follow-up.

Clinical follow-up was performed every 1,3,6 months after the initial procedure. Clinical ,hemodynamic and radiological assessment using SVS WIFI classification, ankle-brachial pressure and duplex ultrasound [at the end of 6months] respectively .

Study end points.

The primary outcome measure was primary patency rate at 6months, defined as freedom from >50% restenosis as indicated by a duplex ultrasound-derived peak systolic velocity ratio of >2.4.[19]

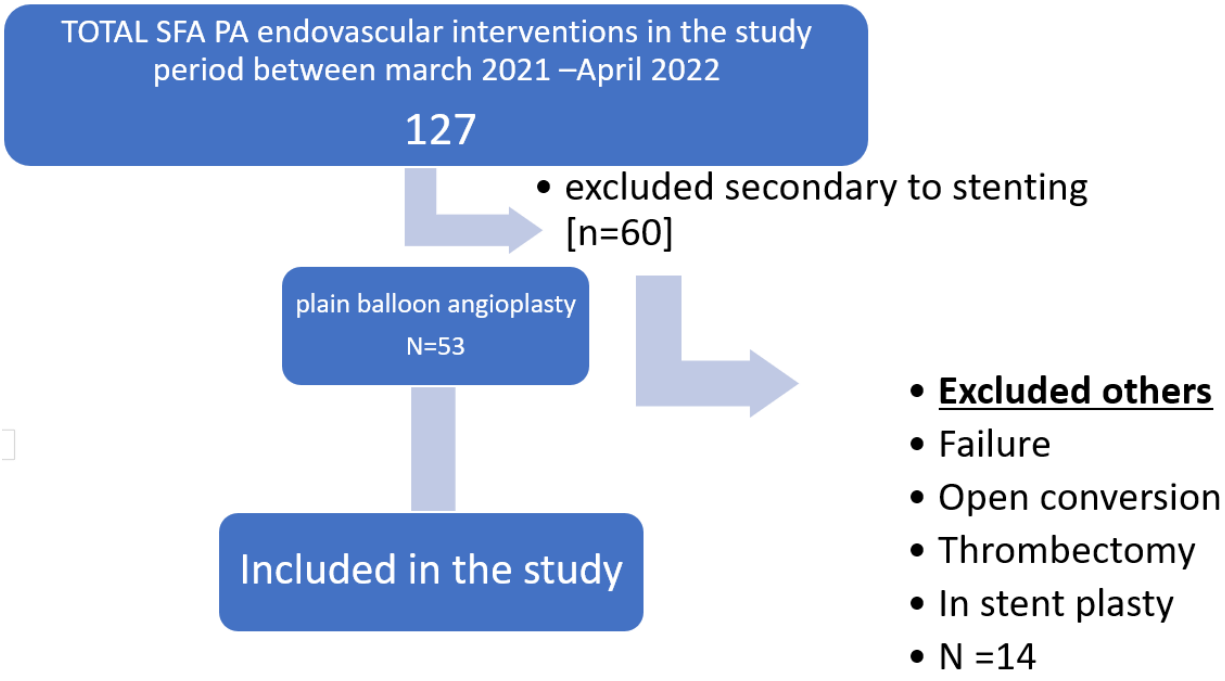
The secondary outcome measures were Above ankle amputation, death at 6 months after the index procedure.

Definitions.

The severity of femoropopliteal lesions was evaluated using the GLASS femoropopliteal grading system. Flow-limiting dissection was defined as dissection with deterioration of the distal antegrade flow. Poor runoff was defined as one or fewer below-the-knee tibial.

RESULTS & DISCUSSION

FLOW CHART OF THE STUDY :[CONSORT DIAGRAM]



Distribution of types of DISSECTION

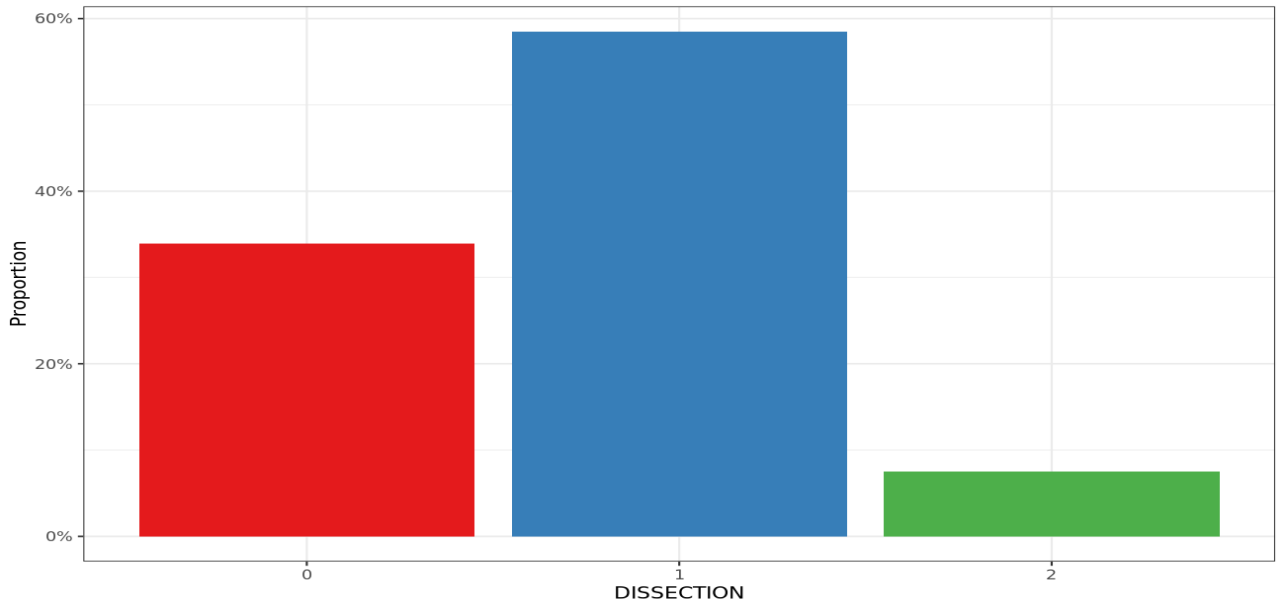


Figure 2

	0	1	2
DISSECTION	18 (34%)	31 (58%)	4 (7.5%)

Table 3

Age distribution

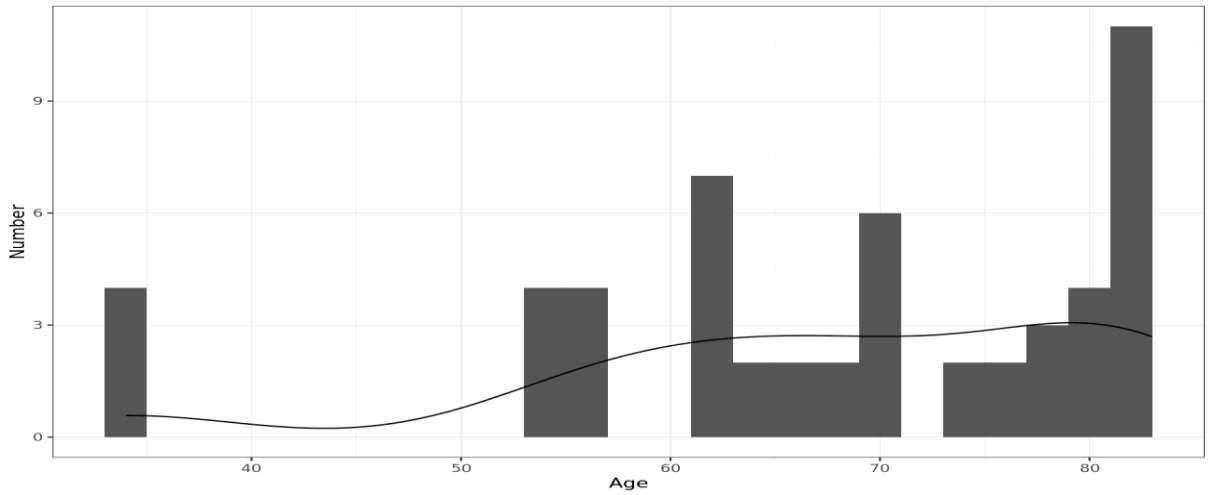


Figure 3Age distribution

	mean (sd)	median [Q25-75]	min	max	n
Age	67.9 (13.6)	70.0 [62.0; 81.0]	34.0	83.0	53

Table 4

Description of the distribution of Age depending on DISSECTION

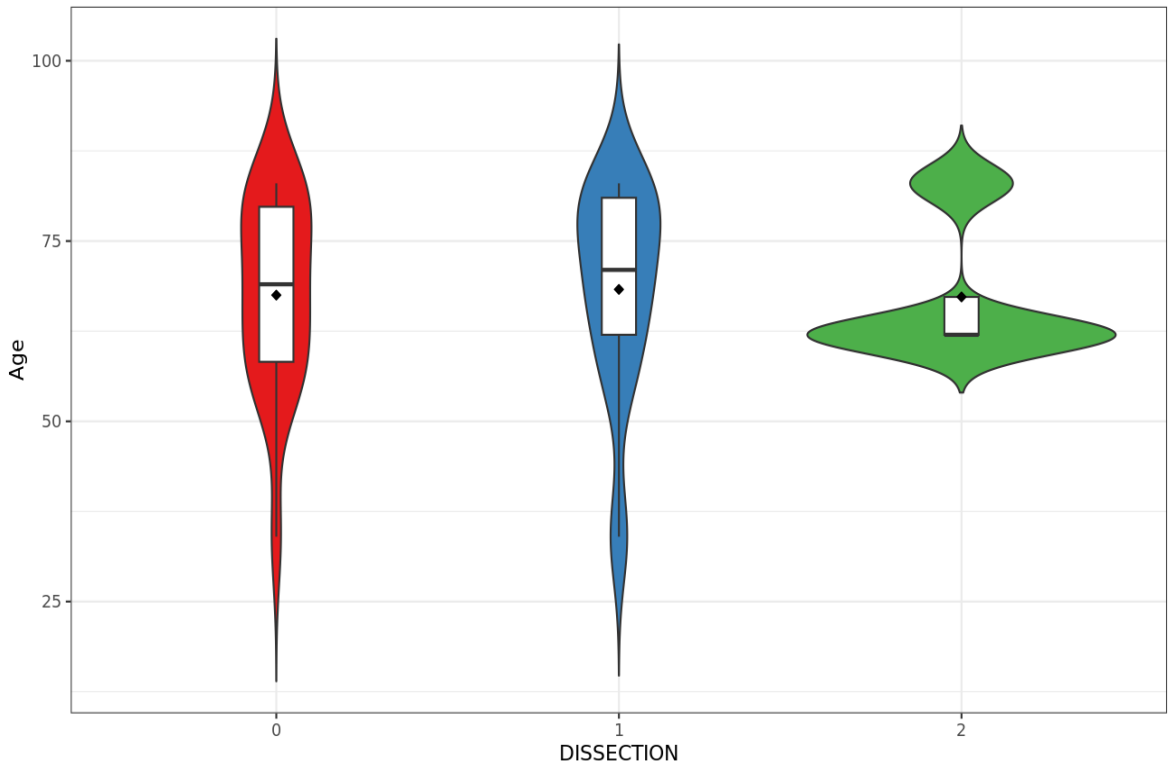


Figure 4Description of the distribution of Age depending on DISSECTION

	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
Age, median [Q25-75]	69.0 [58.2; 79.8]	71.0 [62.0; 81.0]	62.0 [62.0; 67.2]	53	0.85

Table 5

Interpretation

As the numbers of subjects compared were small, a non-parametric test was carried out (Kruskal-Walli's test). The exact interpretation is that the average rank of Age is not significantly different depending on DISSECTION (p = 0.85).

Description of the GENDER

Distribution of GENDER

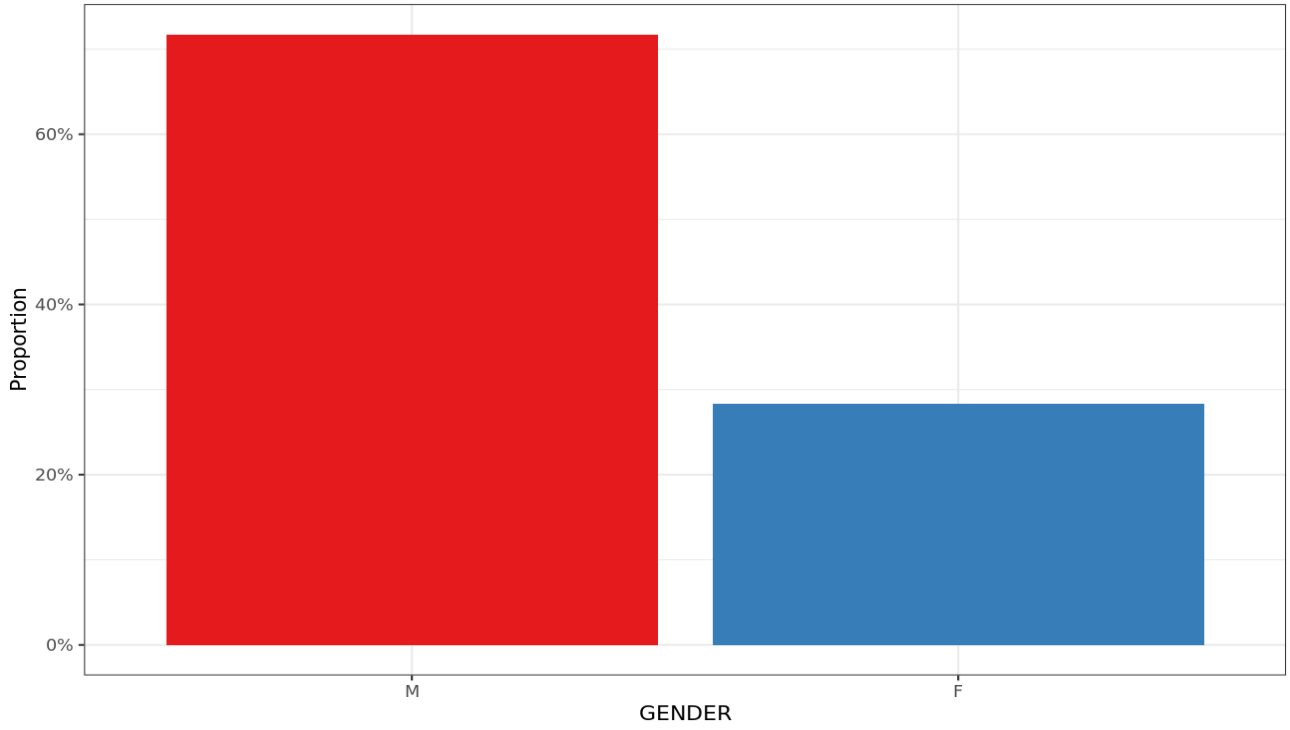


Figure 5Distribution of GENDER

	M	F
GENDER	38 (72%)	15 (28%)

Table 6

Univariable analysis of the distribution of GENDER depending on DISSECTION

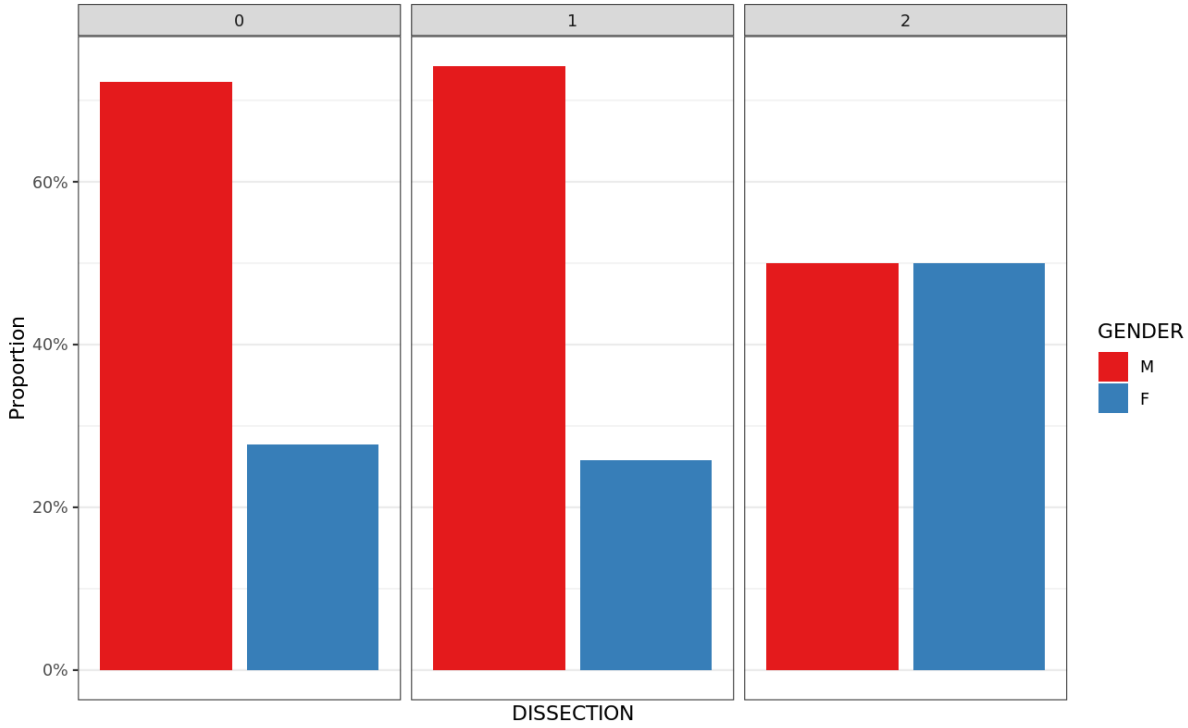


Figure 6Univariable analysis of the distribution of GENDER depending on DISSECTION

	DISSECTION 0 (n = 18)	**DISSECTION 1 (n = 31)**	**DISSECTION 2 (n = 4)**	**n**	**p**
GENDER, n					
M	13 (72%)	23 (74%)	2 (50%)	38	0.71
F	5 (28%)	8 (26%)	2 (50%)	15	-

Table 7

Interpretation

The distribution of GENDER is not significantly different depending on DISSECTION (p = 0.71).

Distribution of CORONARY ARTERY DISEASE

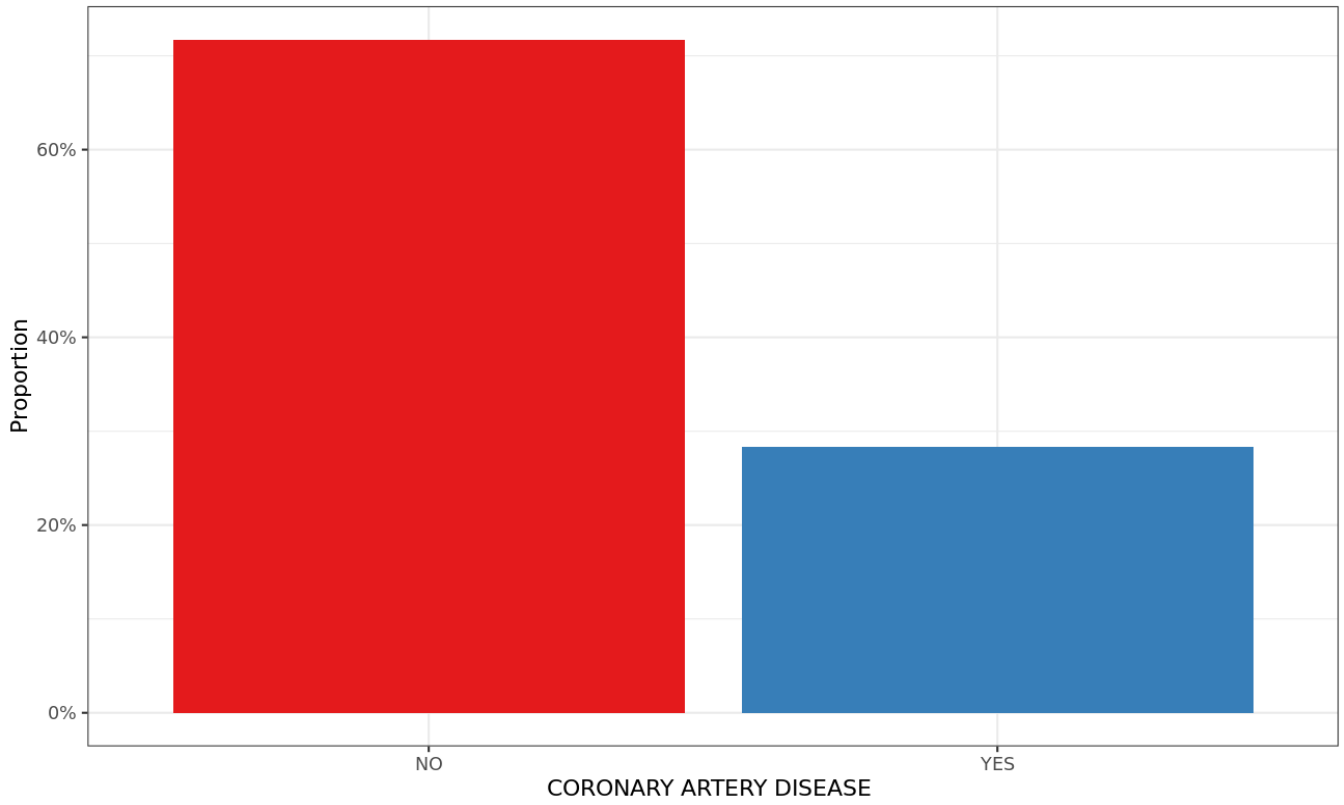


Figure 7Distribution of CORONARY ARTERY DISEASE

	NO	YES
CORONARY ARTERY DISEASE	38 (72%)	15 (28%)

Table 8

Univariable analysis of the distribution of CAD depending on DISSECTION

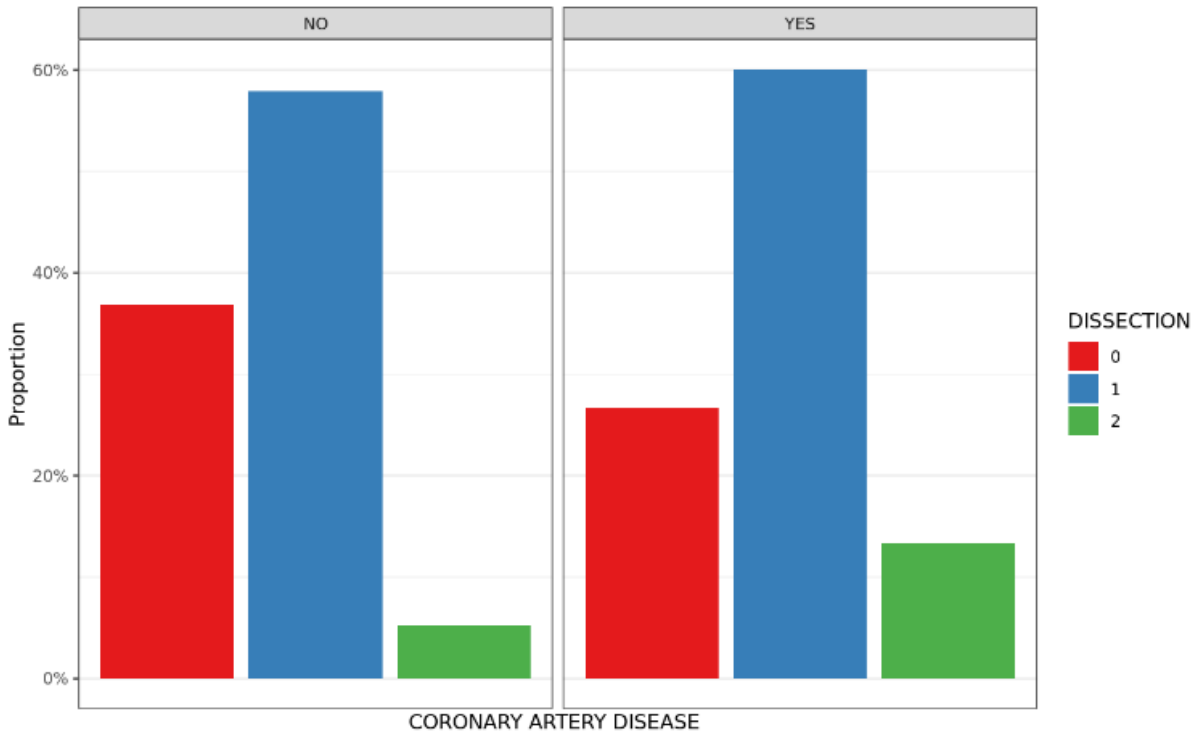


Figure 8Univariable analysis of the distribution of CAD depending on DISSECTION

	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
CORONARY ARTERY DISEASE , n					
NO	14 (37%)	22 (58%)	2 (5.3%)	38	0.52
YES	4 (27%)	9 (60%)	2 (13%)	15	-

Table 9

Interpretation

The distribution of coronary artery disease is not significantly different depending on DISSECTION (p = 0.52).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the CKD

Distribution of CKD

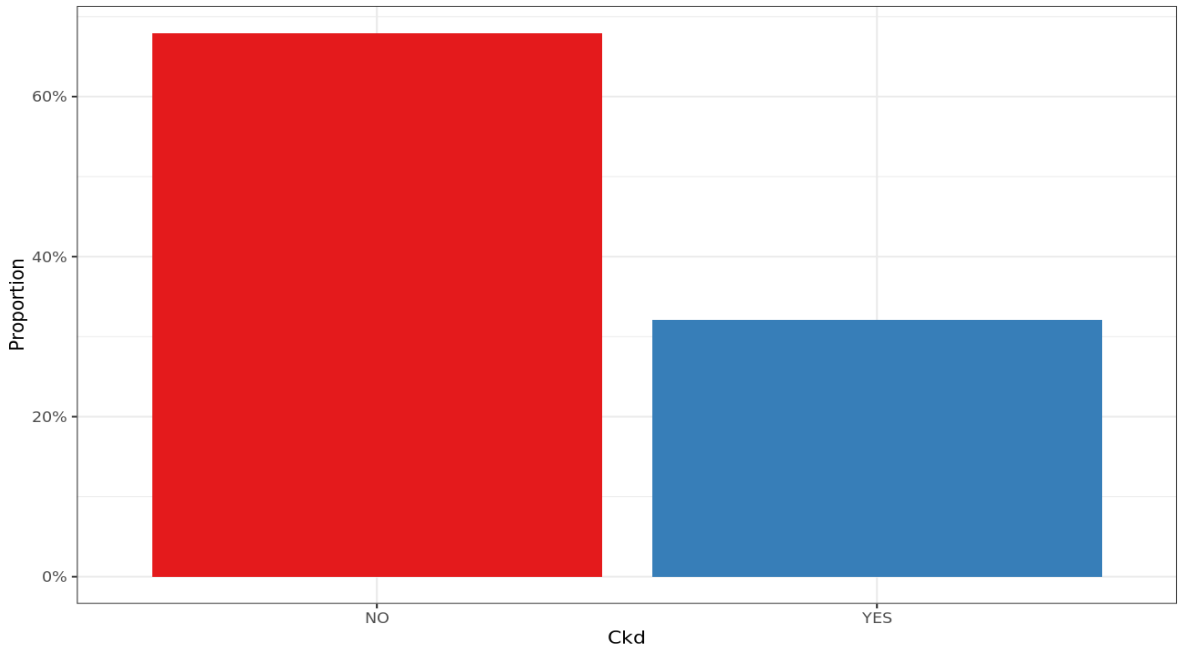


Figure 9

	NO	YES
CKD	36 (68%)	17 (32%)

Table 10

Univariable analysis of the distribution of CKD depending on DISSECTION

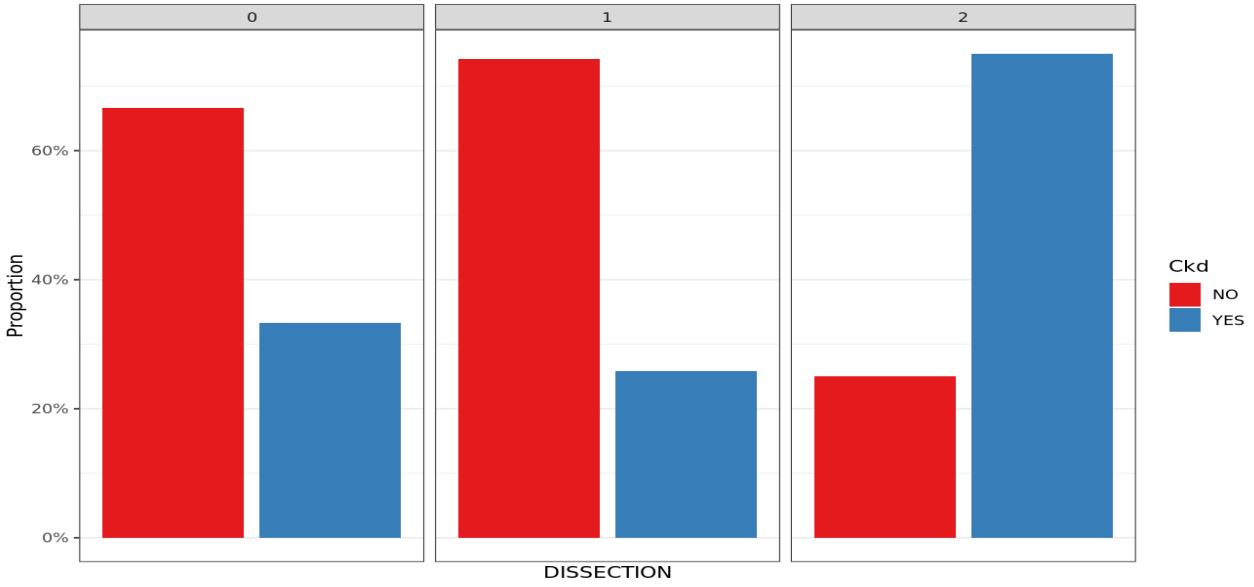


Figure 10

	DISSECTION 0 (n = 18)	**DISSECTION 1 (n = 31)**	**DISSECTION 2 (n = 4)**	**n**	**p**
CKD, n					
NO	12 (67%)	23 (74%)	1 (25%)	36	0.14
YES	6 (33%)	8 (26%)	3 (75%)	17	-

Table 11

Interpretation

The distribution of CKD is not significantly different depending on DISSECTION (p = 0.14).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the CVD [Cerebrovascular disease]

Distribution of CVD [Cerebrovascular disease]

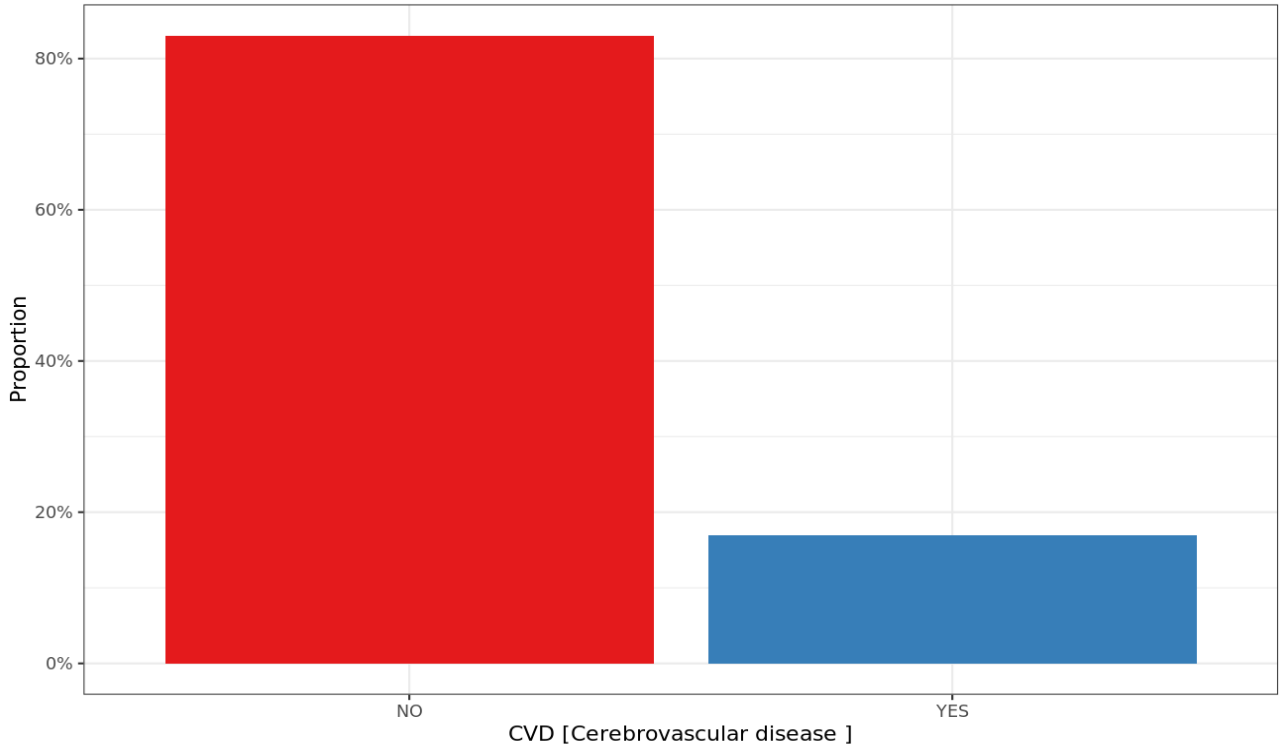


Figure 11

	NO	YES
CVD [Cerebrovascular disease]	44 (83%)	9 (17%)

Table 12

Univariable analysis of the distribution of CVD [Cerebrovascular disease] depending on DISSECTION

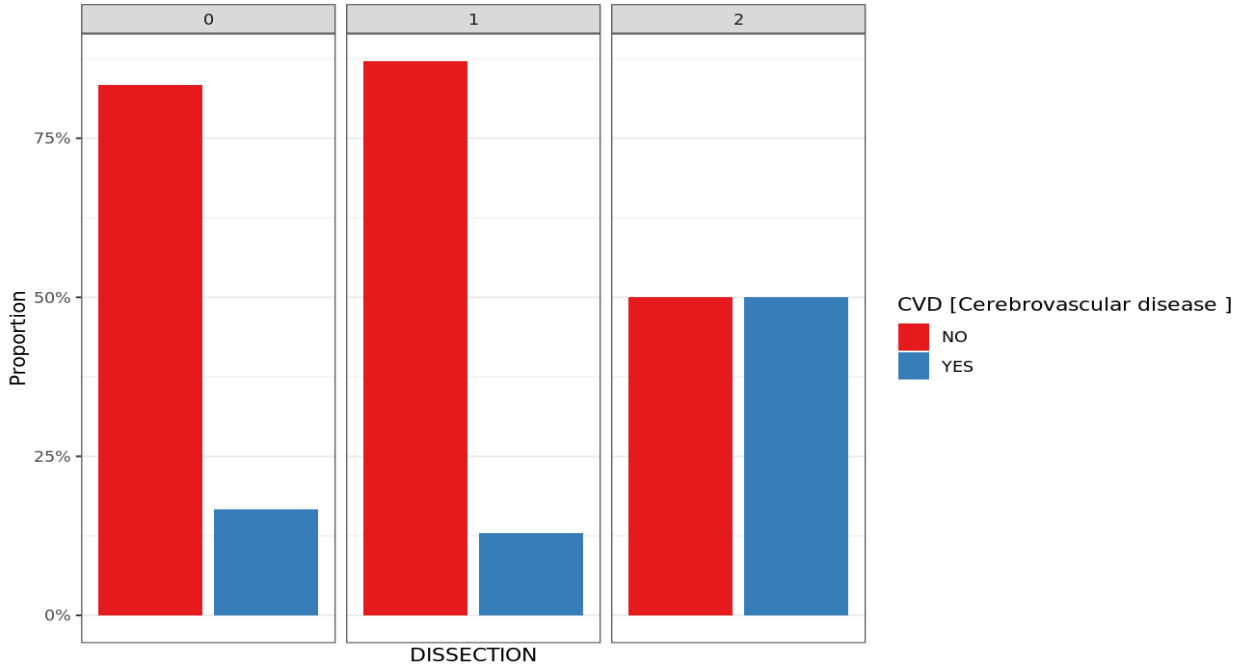


Figure 12

	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
CVD					
NO	15 (83%)	27 (87%)	2 (50%)	44	0.2
YES	3 (17%)	4 (13%)	2 (50%)	9	-

Table 13

Interpretation

The distribution of CVD [Cerebrovascular disease] is not significantly different depending on DISSECTION (p = 0.2).n

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the DIALYSIS

Distribution of DIALYSIS

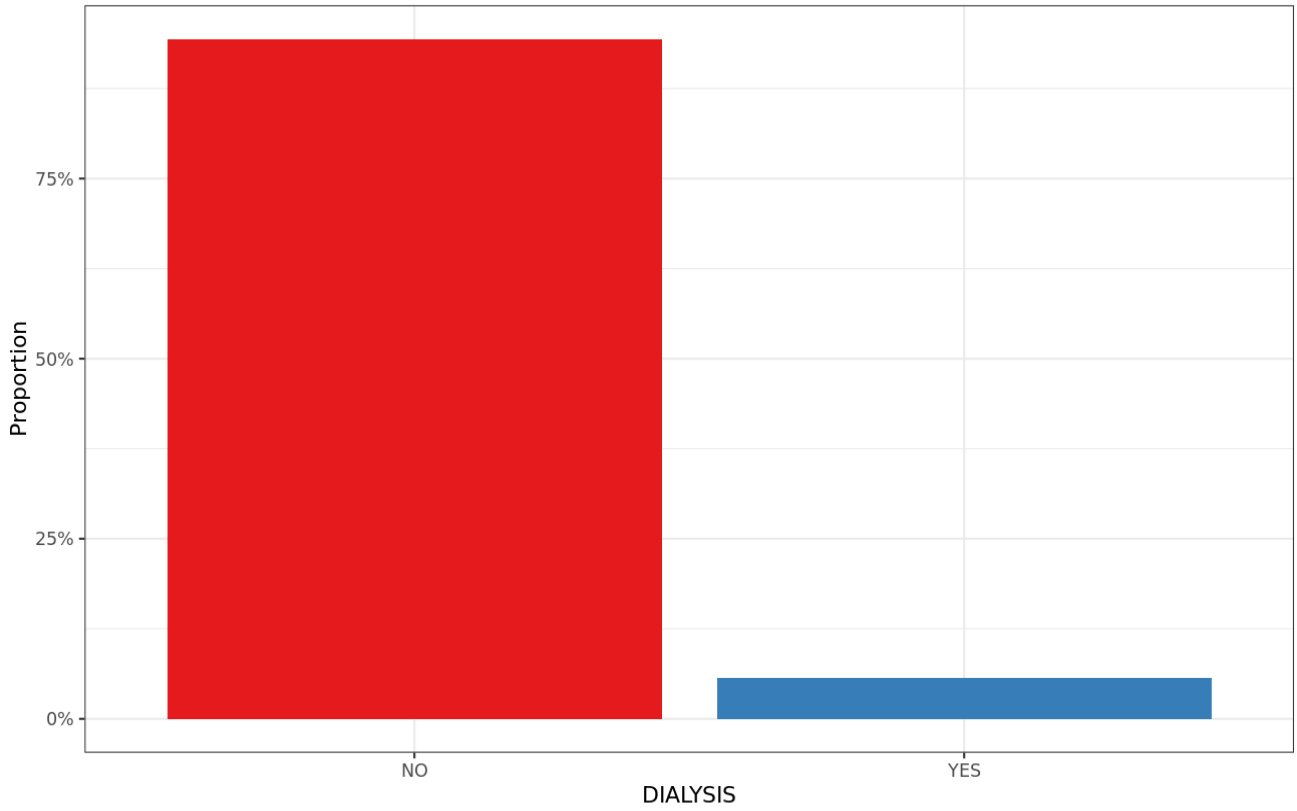


Figure 13

	NO	YES
DIALYSIS	50 (94%)	3 (5.7%)

Table 14

Univariable analysis of the distribution of DIALYSIS depending on DISSECTION

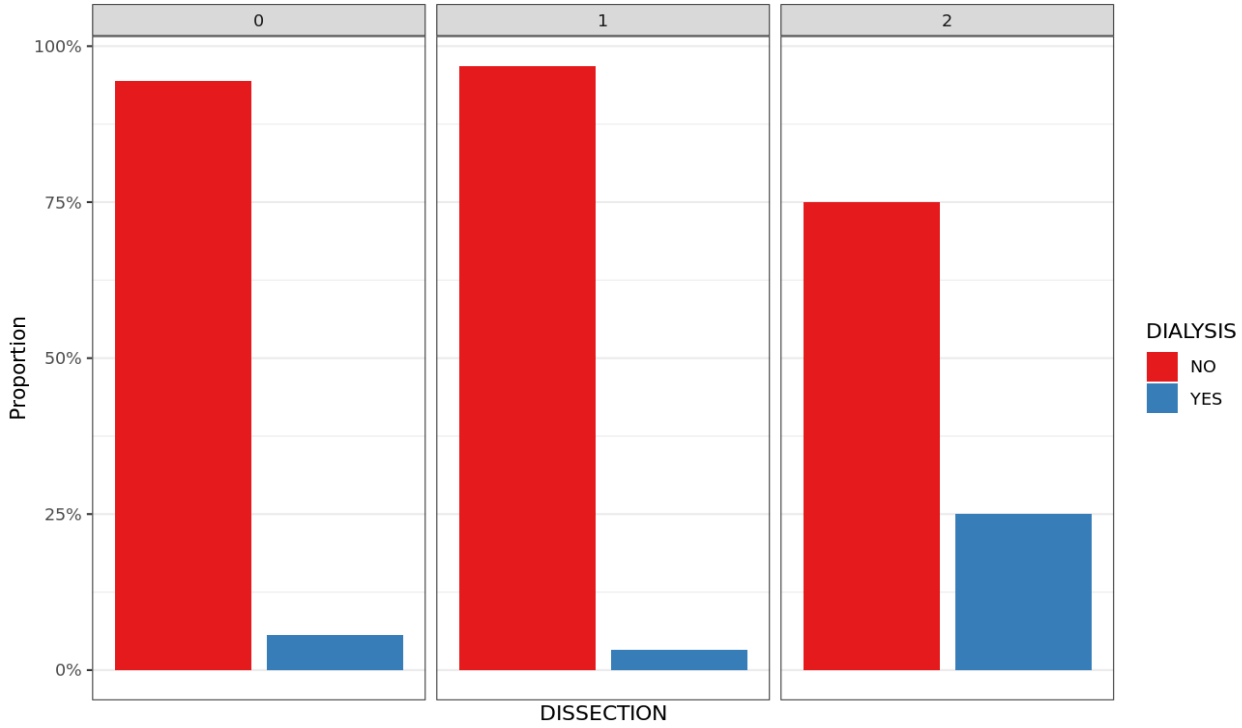


Figure 14

	DISSECTION 0 (n = 18)	**DISSECTION 1 (n = 31)**	**DISSECTION 2 (n = 4)**	**n**	**p**
DIALYSIS, n					
NO	17 (94%)	30 (97%)	3 (75%)	50	0.25
YES	1 (5.6%)	1 (3.2%)	1 (25%)	3	-

Table 15

Interpretation

The distribution of DIALYSIS is not significantly different depending on DISSECTION (p = 0.25).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the DM

Distribution of Dm

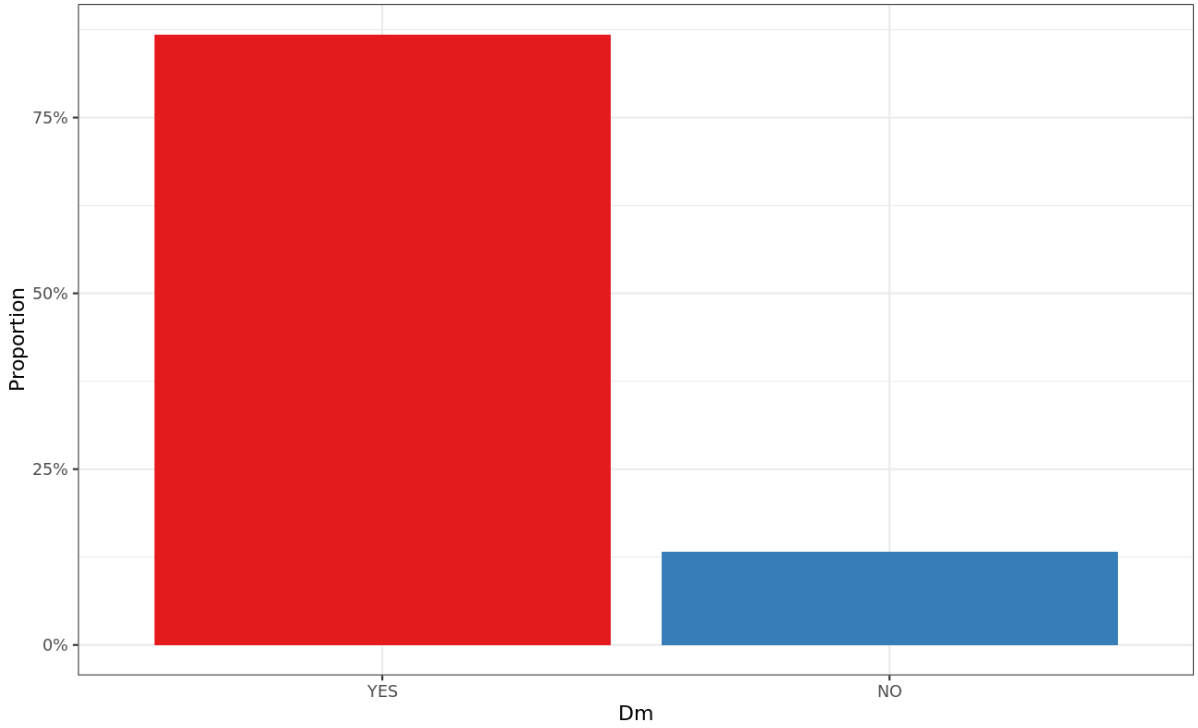


Figure 15

	YES	NO
Dm	46 (87%)	7 (13%)

Table 16

Univariable analysis of the distribution of DM depending on DISSECTION

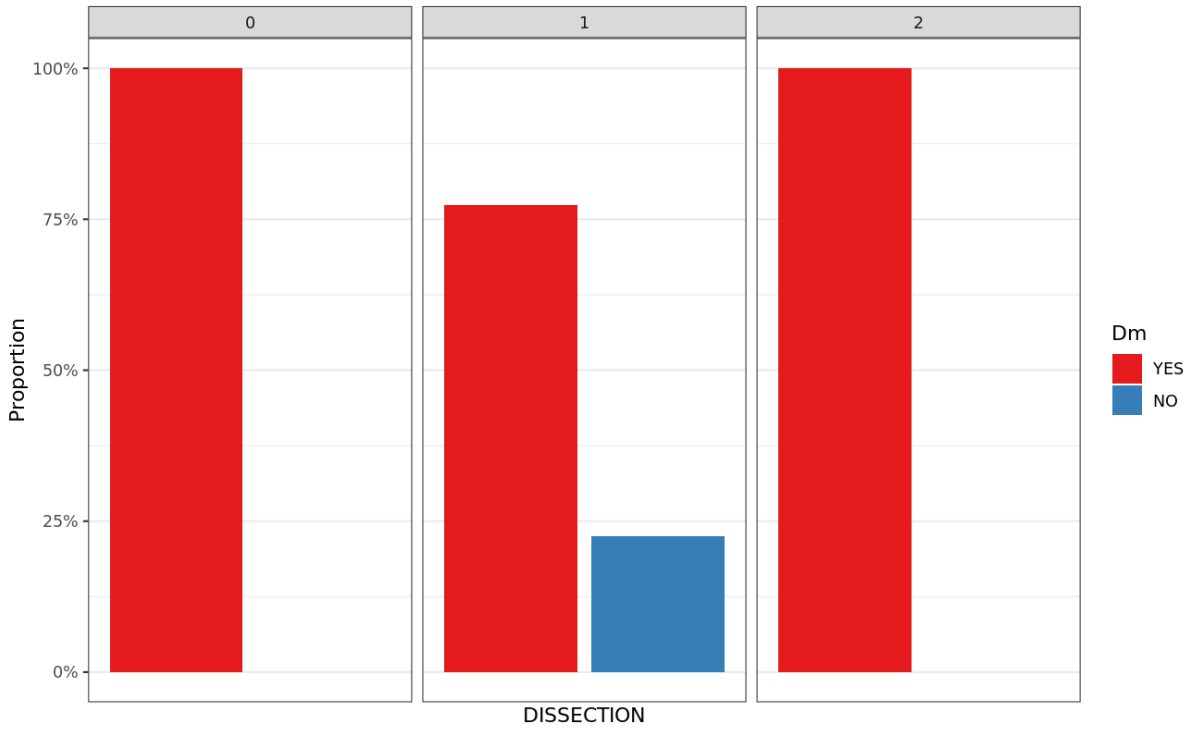


Figure 16

	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
Dm, n					
YES	18 (100%)	24 (77%)	4 (100%)	46	0.059
NO	0 (0%)	7 (23%)	0 (0%)	7	-

Table 17

Interpretation

The distribution of Dm is not significantly different depending on DISSECTION (p = 0.059).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the Dyslipidaemia

Distribution of Dyslipidaemia

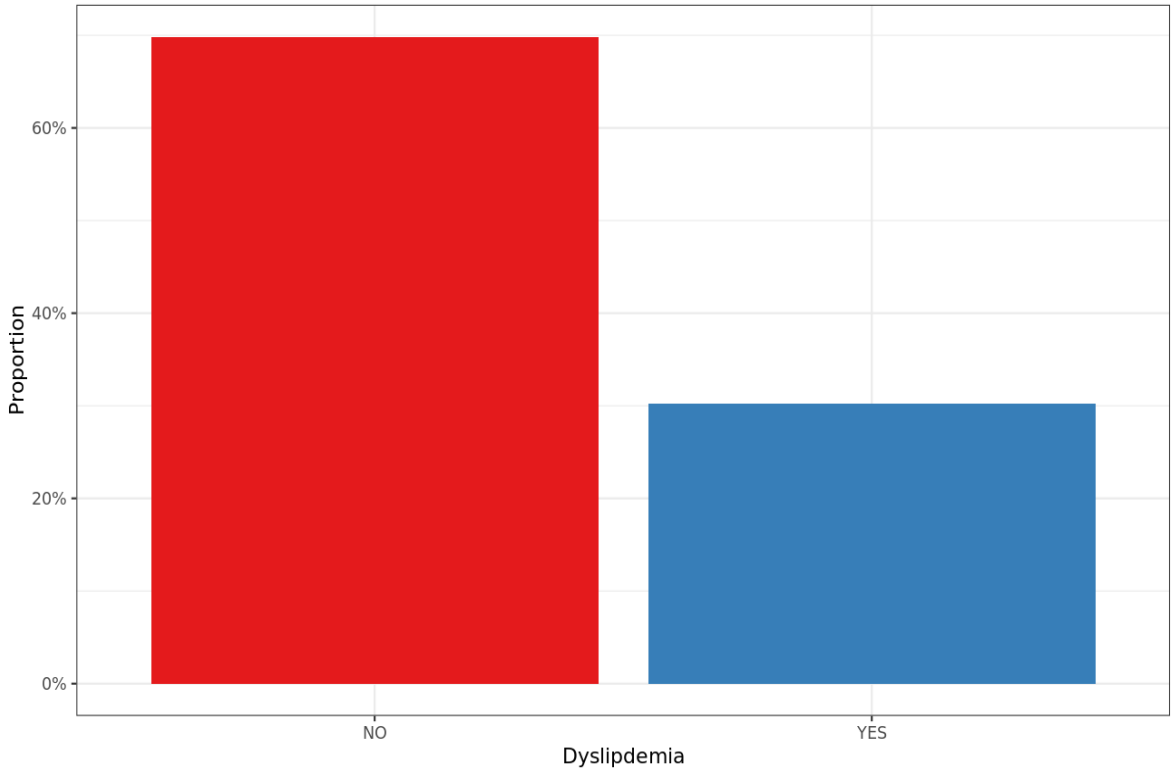
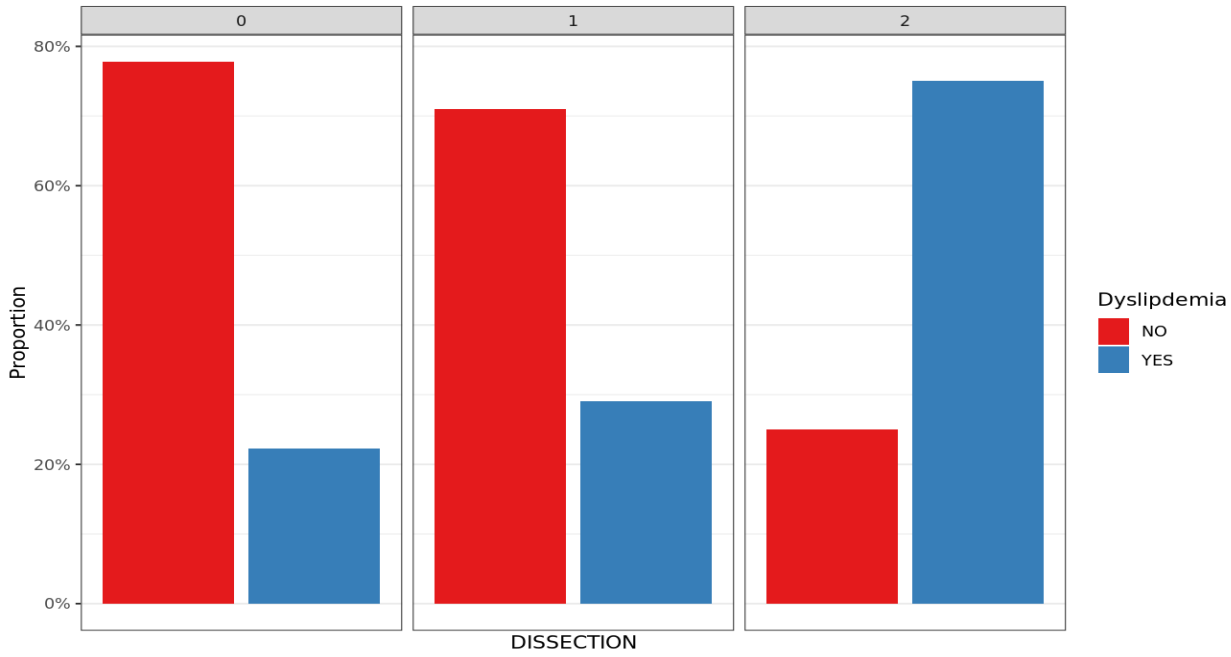


Figure 17

	NO	YES
Dyslipidaemia	37 (70%)	16 (30%)

Table 18

Univariable analysis of the distribution of Dyslipidaemia depending on DISSECTION



	DISSECTION 0 (n = 18)	**DISSECTION 1 (n = 31)**	**DISSECTION 2 (n = 4)**	**n**	**p**
Dyslipidaemia, n					
NO	14 (78%)	22 (71%)	1 (25%)	37	0.13
YES	4 (22%)	9 (29%)	3 (75%)	16	-

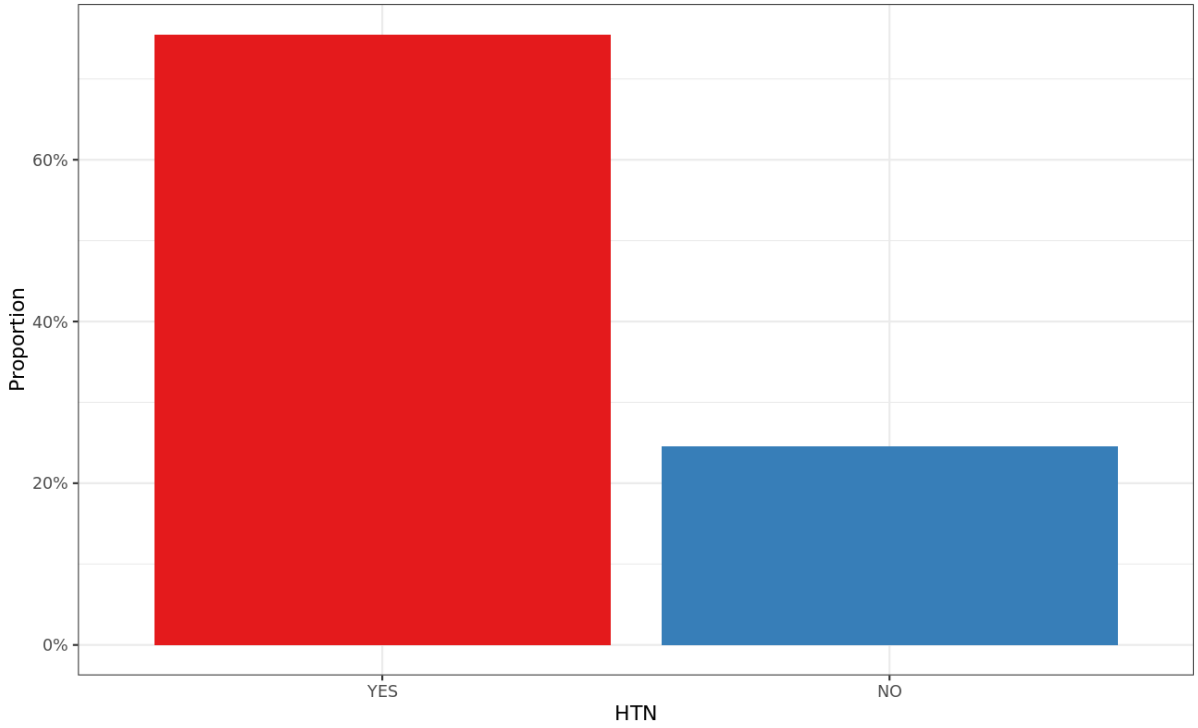
Interpretation

The distribution of Dyslipidaemia is not significantly different depending on DISSECTION (p = 0.13).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

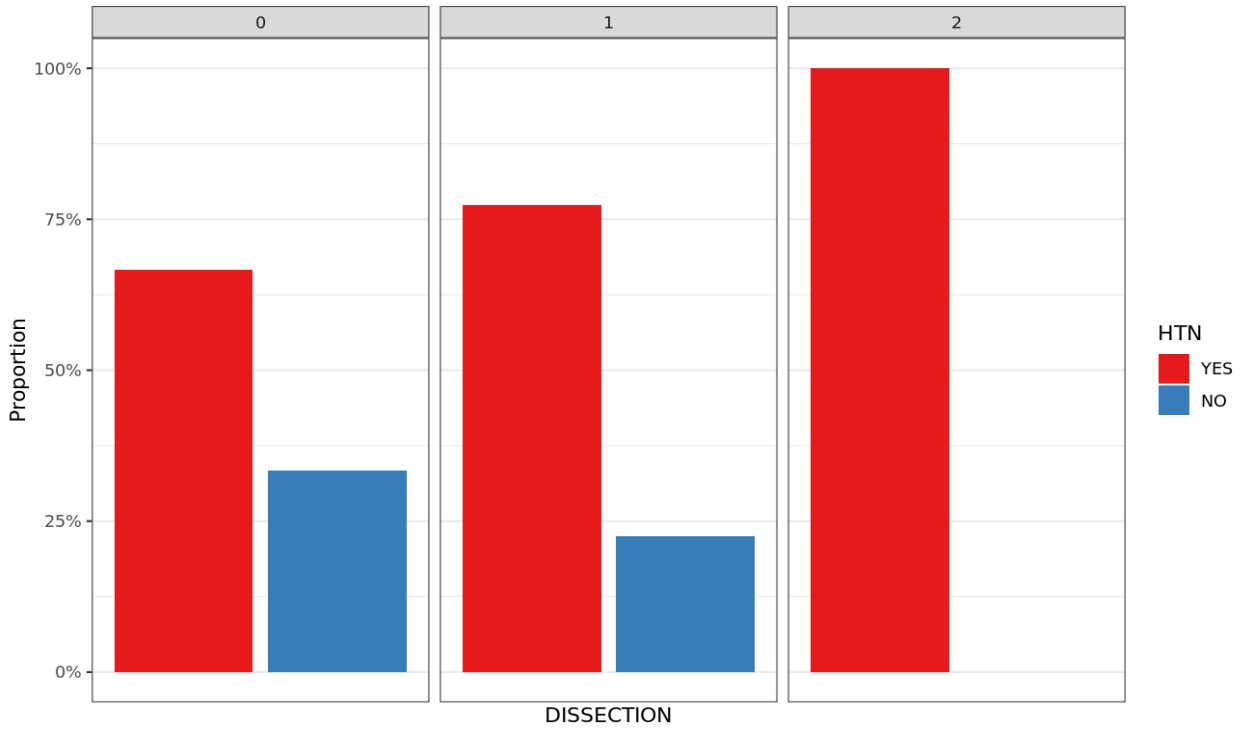
Description of the variable HTN

Distribution of HTN



	YES	NO
HTN	40 (75%)	13 (25%)

Univariable analysis of the distribution of HTN depending on DISSECTION



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
HTN, n					
YES	12 (67%)	24 (77%)	4 (100%)	40	0.48
NO	6 (33%)	7 (23%)	0 (0%)	13	-

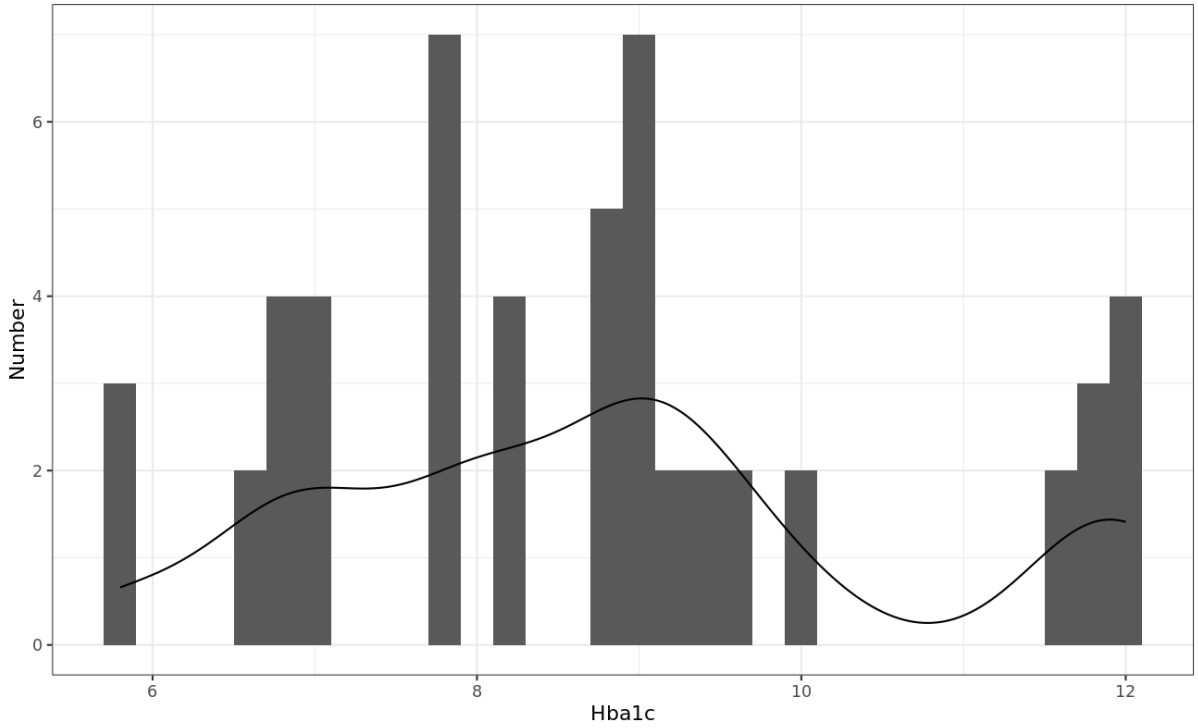
Interpretation

The distribution of HTN is not significantly different depending on DISSECTION (p = 0.48).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

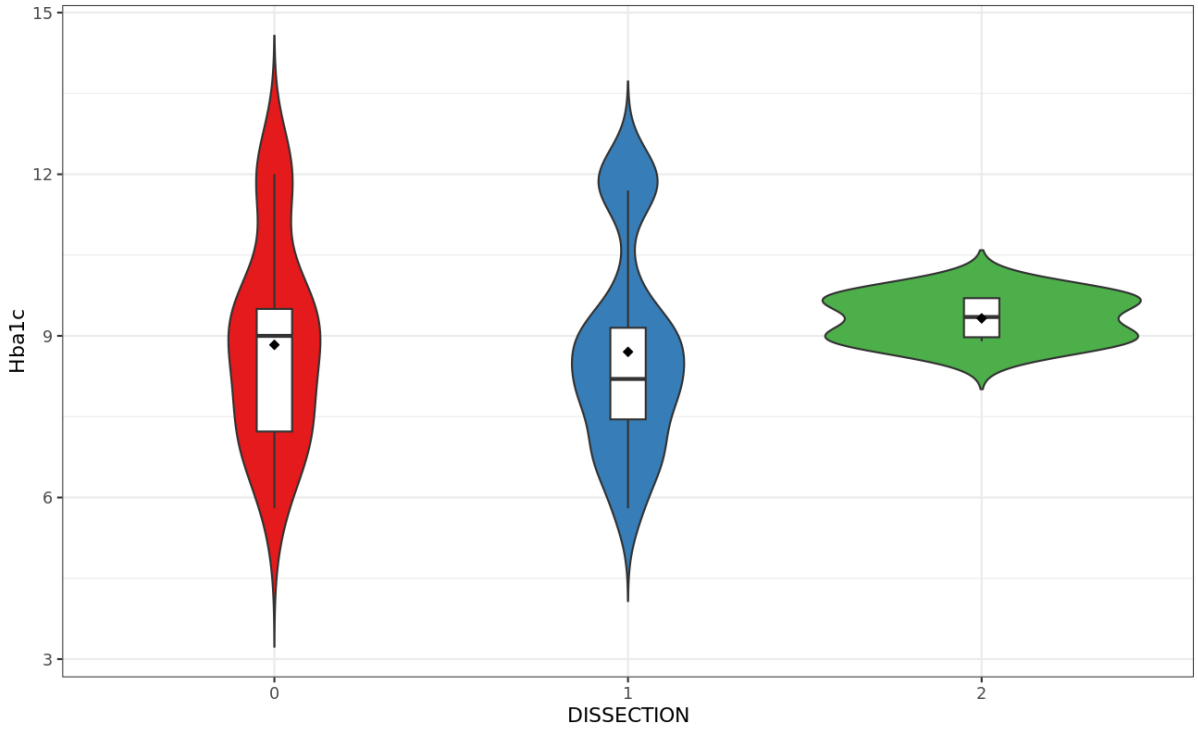
Description of the variable HbA1c

Hba1c distribution



	mean (SD)	median [Q25-75]	min	max	n
Hba1c	8.79 (1.78)	8.90 [7.90; 9.50]	5.80	12.0	53

Description of the distribution of HbA1c depending on DISSECTION



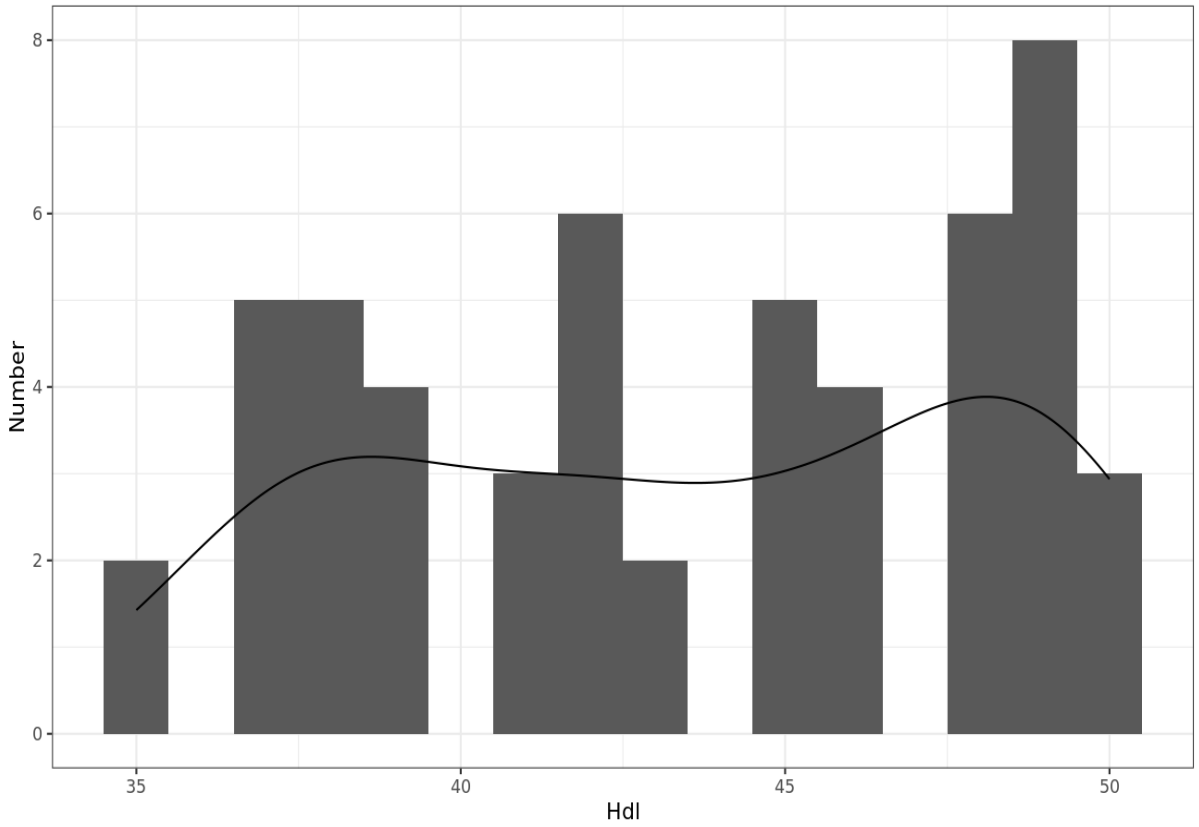
	DISSECTION 0 (n = 18)	**DISSECTION 1 (n = 31)**	**DISSECTION 2 (n = 4)**	**n**	**p**
Hba1c, median [Q25-75]	9.00 [7.22; 9.50]	8.20 [7.45; 9.15]	9.35 [8.97; 9.70]	53	0.41

Interpretation

As the numbers of subjects compared were small, a non-parametric test was carried out (Kruskal-Walli's test). The exact interpretation is that the average rank of Hba1c is not significantly different depending on DISSECTION (p = 0.41).

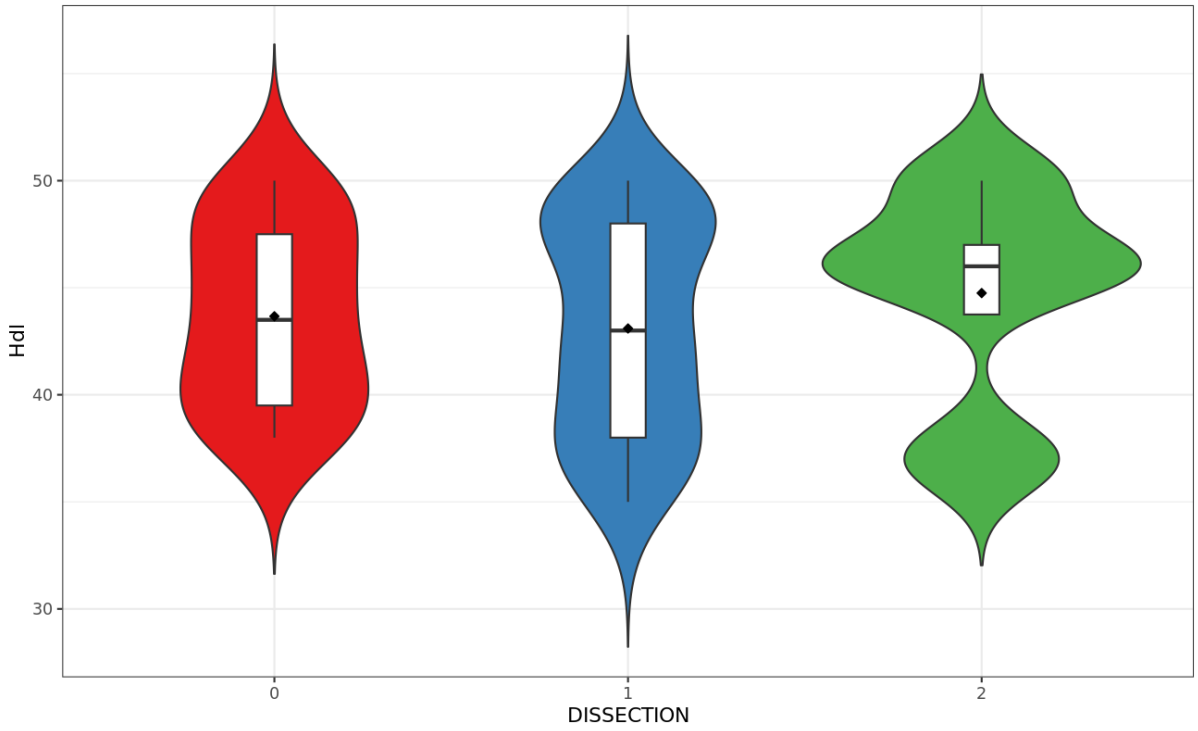
Description of the variable HDL

HDL distribution



	mean (SD)	median [Q25-75]	min	max	n
HDL	44 (20.1)	60.0 [44.0; 89.0]	28.0	100	53

Description of the distribution of HDL depending on DISSECTION



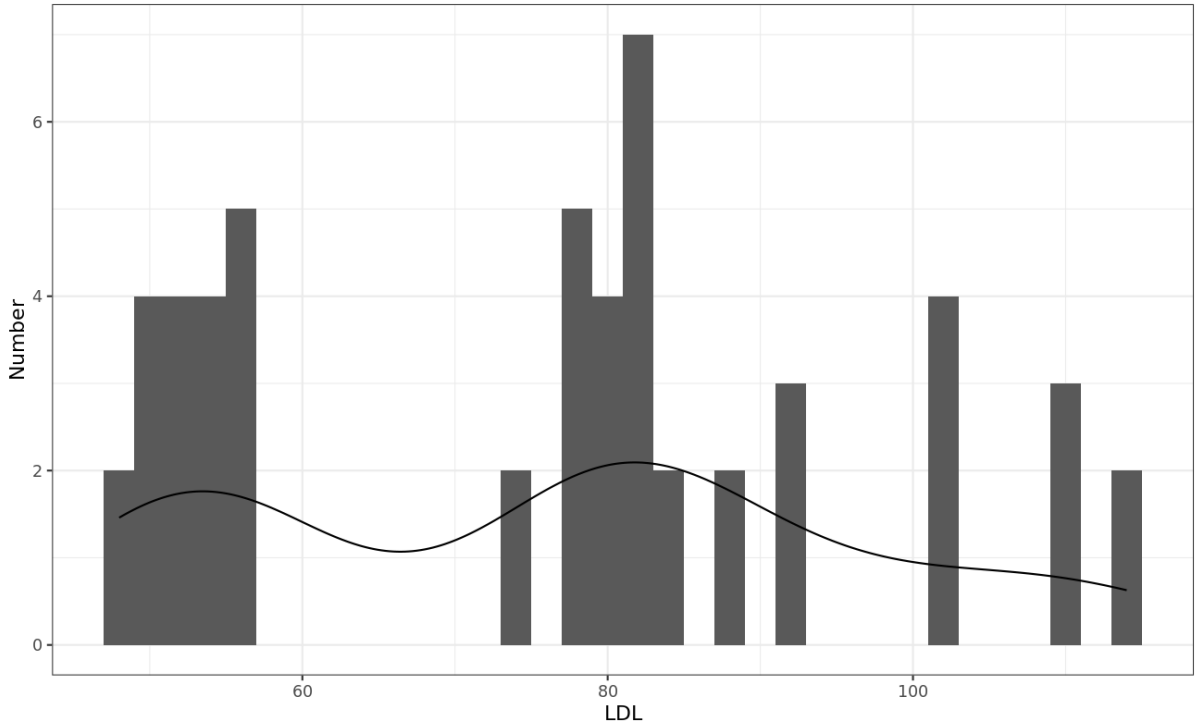
	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
HDL, median [Q25-75]	43.5 [39.5; 47.5]	43.0 [38.0; 48.0]	46.0 [43.8; 47.0]	53	0.74

Interpretation

As the numbers of subjects compared were small, a non-parametric test was carried out (Kruskal-Walli's test). The exact interpretation is that the average rank of HDL is not significantly different depending on DISSECTION (p = 0.74).

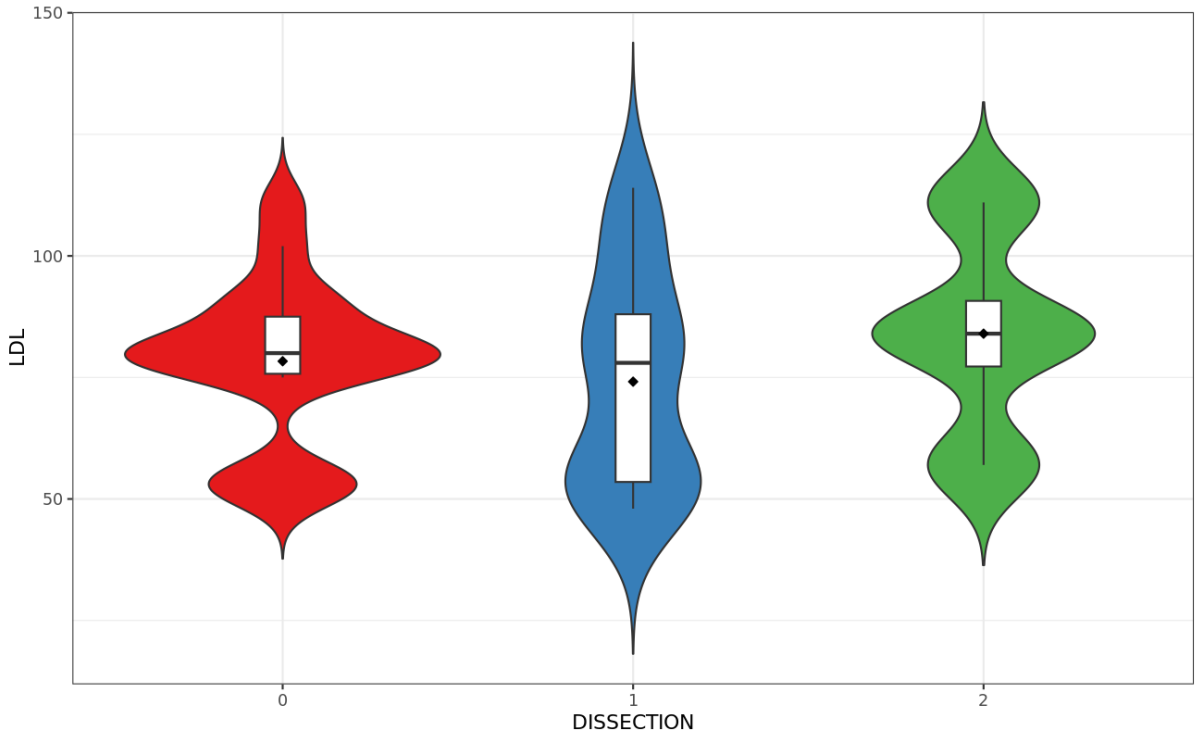
Description of the variable LDL

LDL distribution



	mean (SD)	median [Q25-75]	min	max	n
LDL	76.3 (20.1)	80.0 [54.0; 89.0]	48.0	114	53

Description of the distribution of LDL depending on DISSECTION



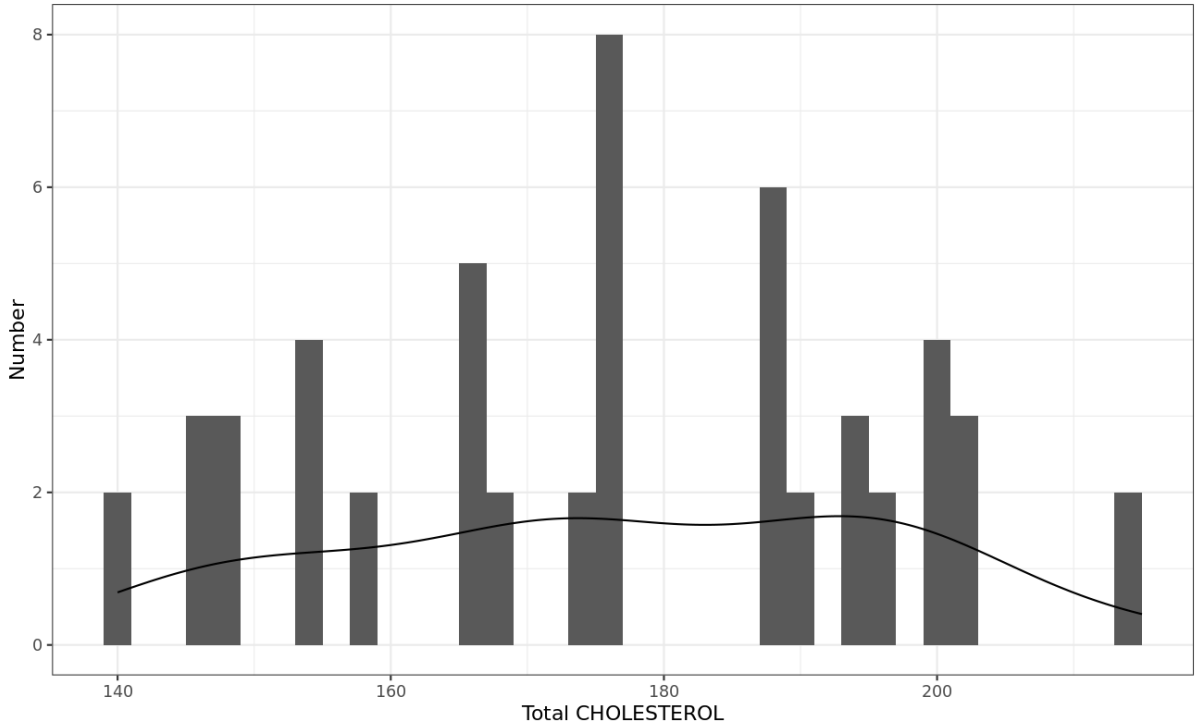
	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
LDL	80.0 [75.8; 87.5]	78.0 [53.5; 88.0]	84.0 [77.2; 90.8]	53	0.39

Interpretation

As the numbers of subjects compared were small, a non-parametric test was carried out (Kruskal-Wallis test). The exact interpretation is that the average rank of LDL is not significantly different depending on DISSECTION (p = 0.39).

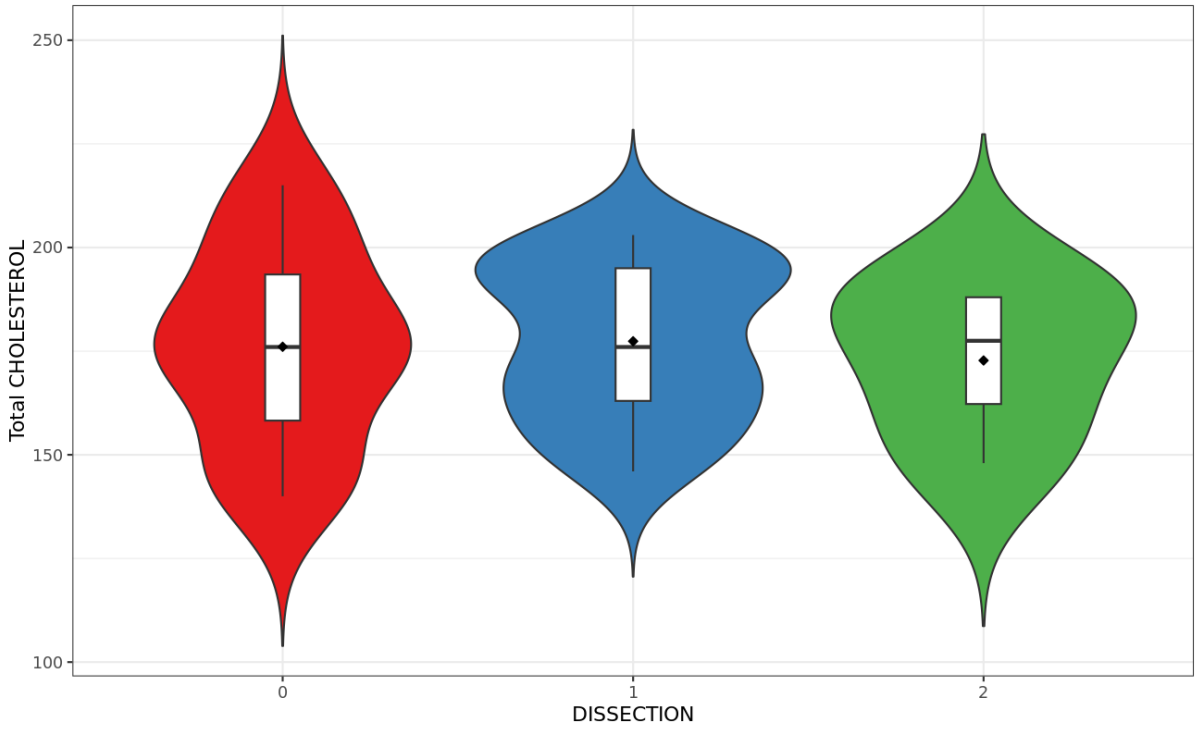
Description of the variable Total CHOLESTEROL

Total CHOLESTEROL distribution



	mean (SD)	median [Q25-75]	min	max	n
Total CHOLESTEROL	177 (20.3)	176 [159; 195]	140	215	53

Description of the distribution of Total CHOLESTEROL depending on DISSECTION



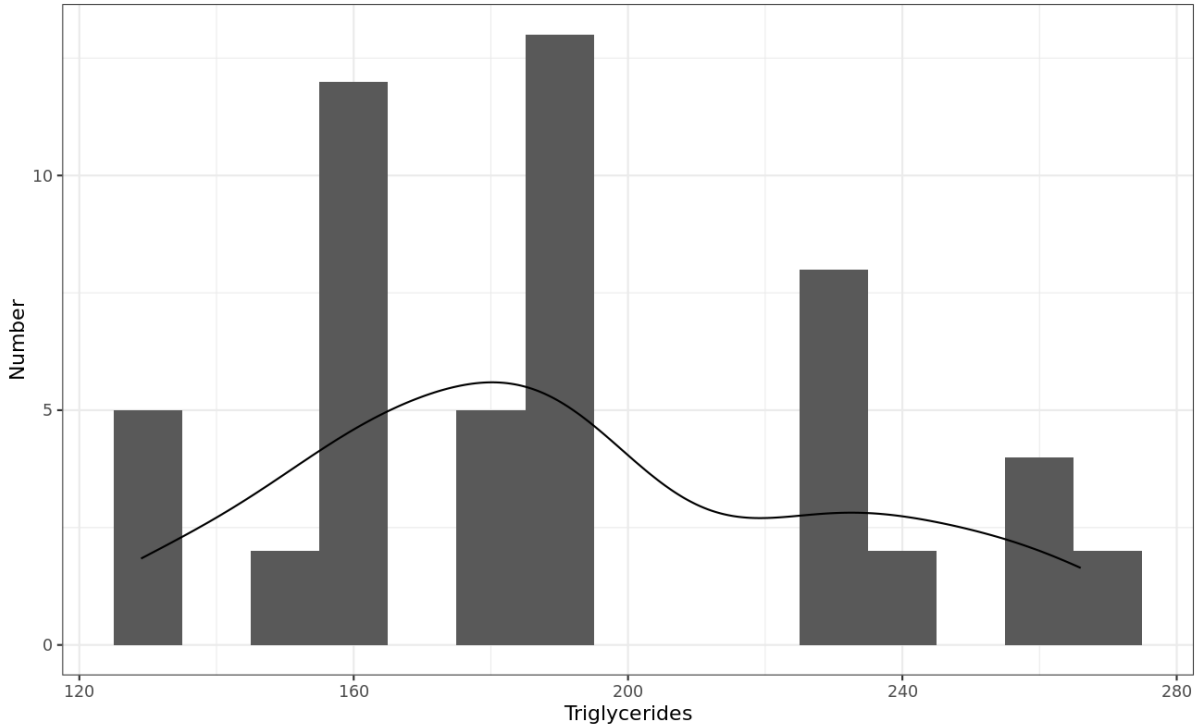
	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
Total CHOLESTEROL	166 [158; 194]	176 [163; 195]	178 [162; 188]	53	0.8

Interpretation

As the numbers of subjects compared were small, a non-parametric test was carried out (Kruskal-Wallis test). The exact interpretation is that the average rank of Total CHOLESTEROL is not significantly different depending on DISSECTION (p = 0.8).

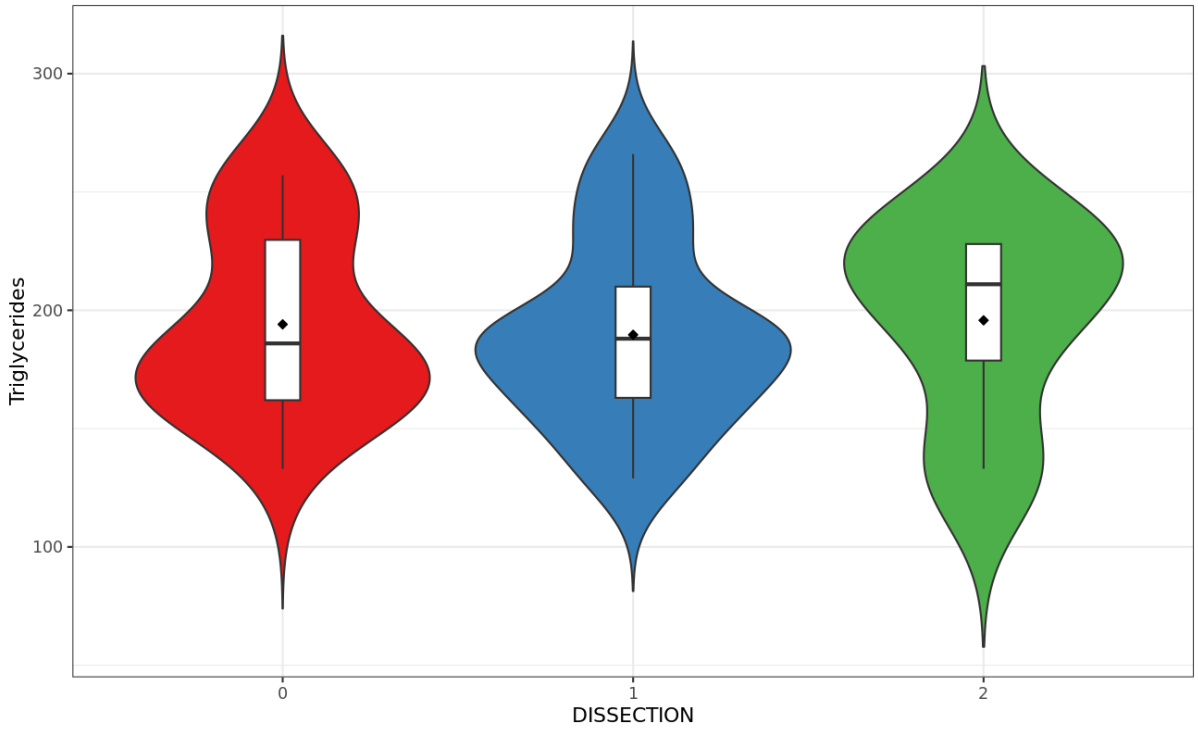
Description of the variable Triglycerides

Triglycerides distribution



	mean (SD)	median [Q25-75]	min	max	n
Triglycerides	192 (38.4)	188 [162; 226]	129	266	53

Description of the distribution of Triglycerides depending on DISSECTION



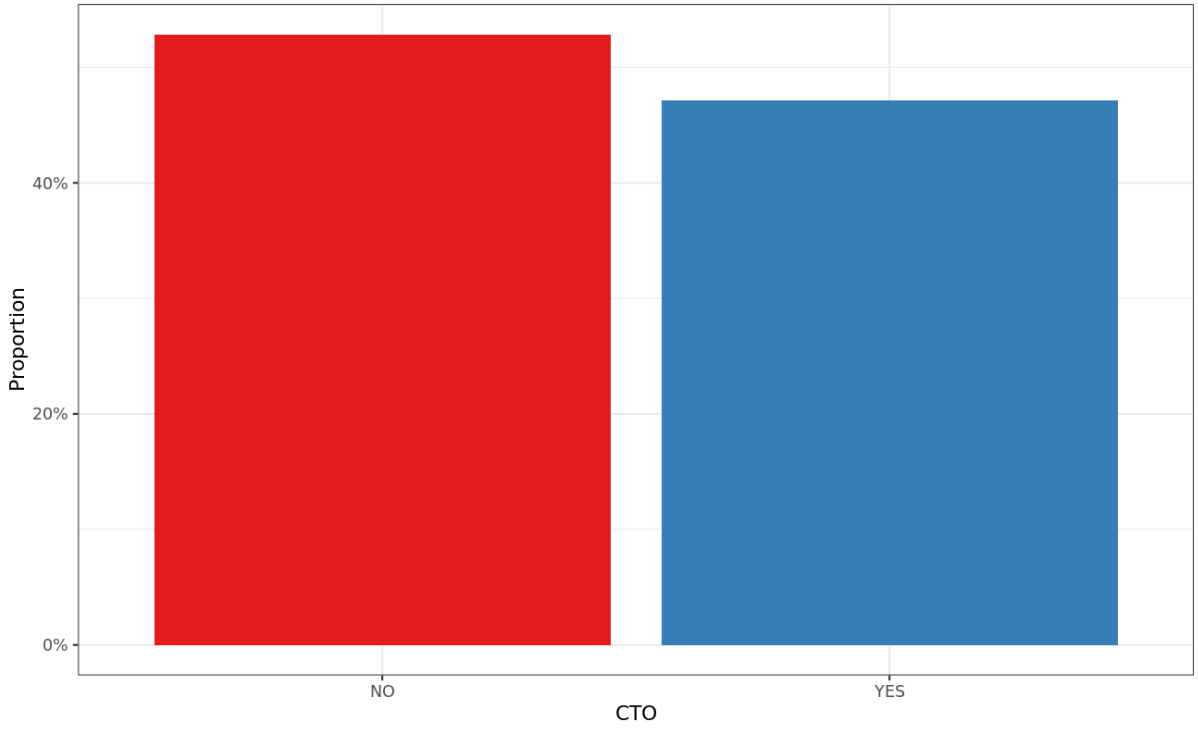
	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
Triglycerides	196 [162; 230]	188 [163; 210]	211 [179; 228]	53	0.86

Interpretation

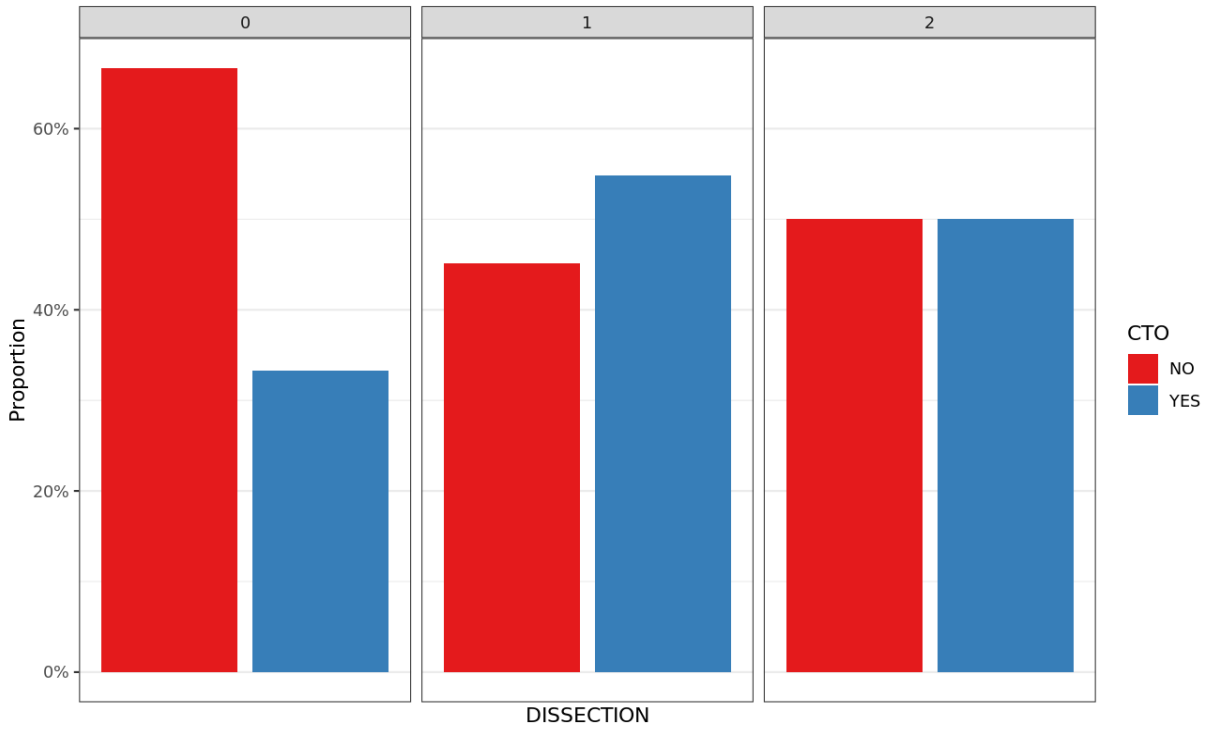
As the numbers of subjects compared were small, a non-parametric test was carried out (Kruskal-Wallis test). The exact interpretation is that the average rank of Triglycerides is not significantly different depending on DISSECTION (p = 0.86).

Description of the femoropopliteal CTO

Distribution of CTO



	NO[NO DISSECTION]	YES
CTO	28 (53%)	25 (47%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
CTO, n					
NO	12 (67%)	14 (45%)	2 (50%)	28	0.36
YES	6 (33%)	17 (55%)	2 (50%)	25	-

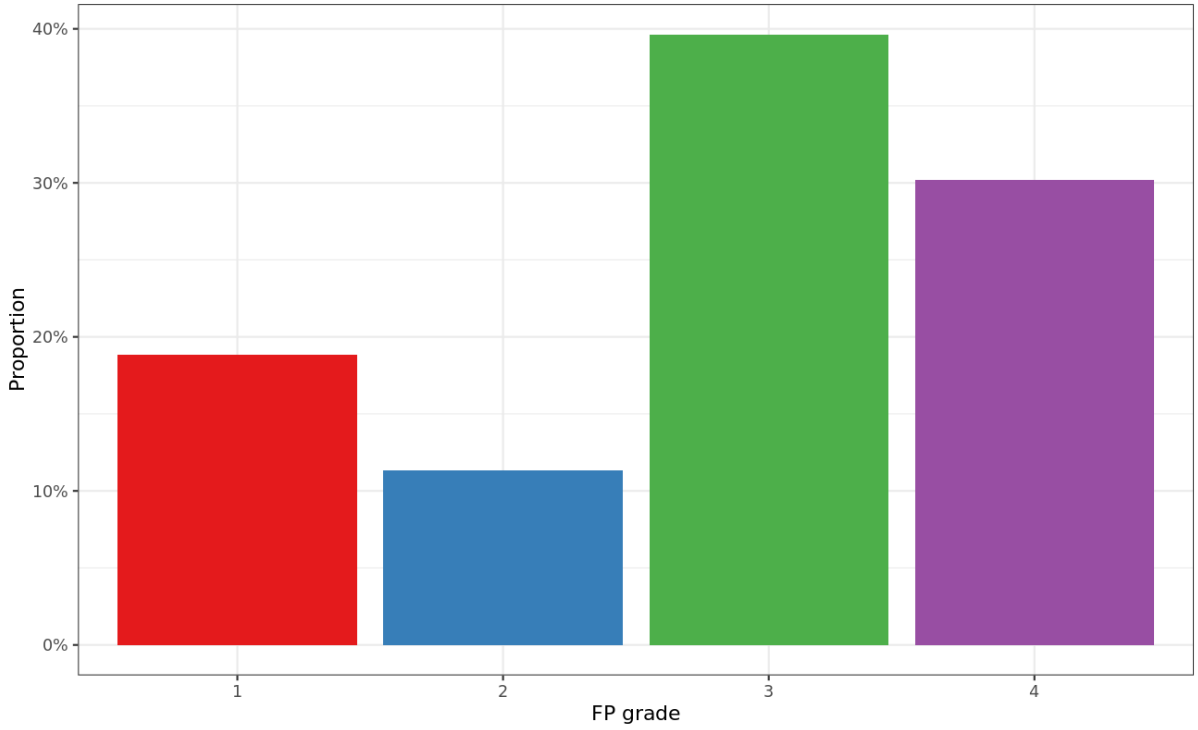
Interpretation

The distribution of CTO is not significantly different depending on DISSECTION (p = 0.36).

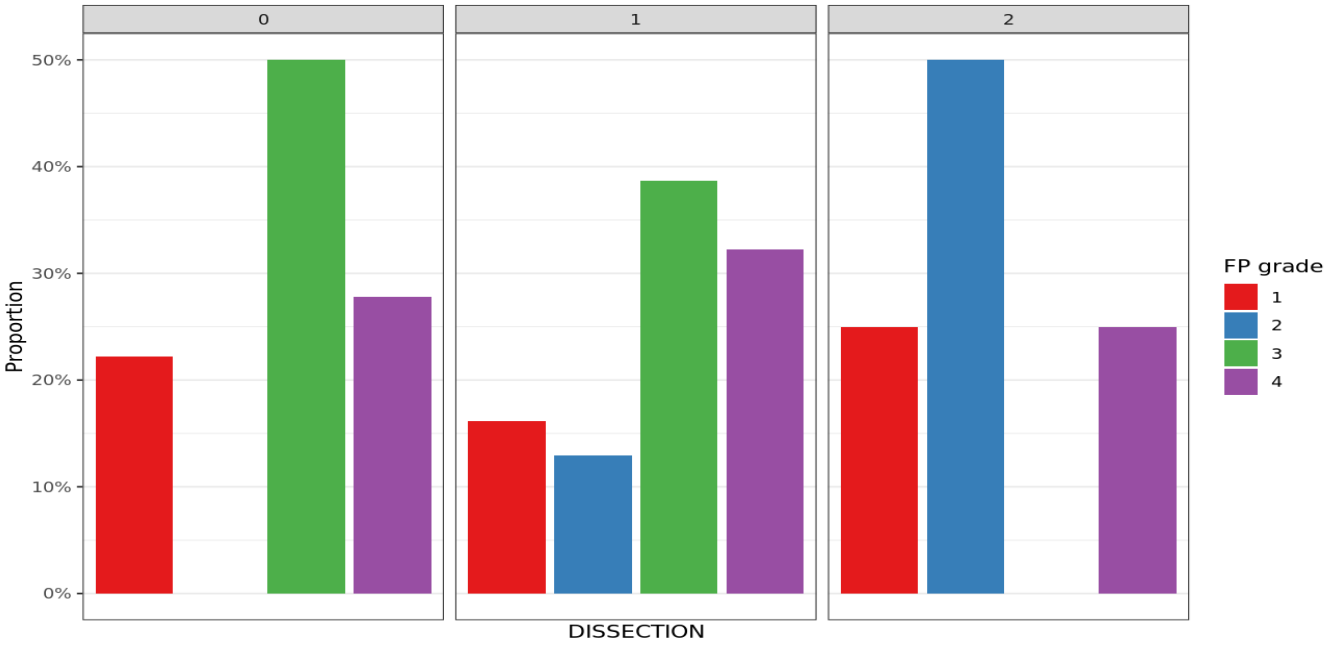
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the FP grade

Distribution of FP grade according to GLASS



	1	2	3	4
FP grade	10 (19%)	6 (11%)	21 (40%)	16 (30%)



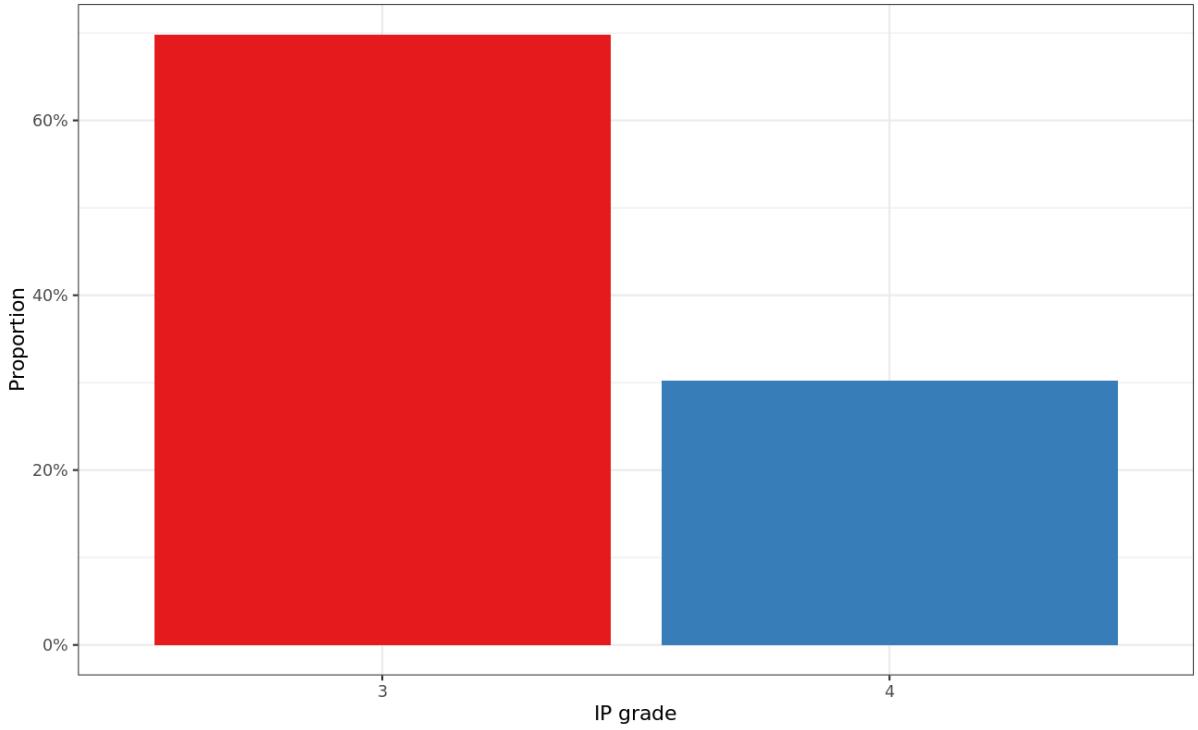
	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
FP grade, n					
1	4 (22%)	5 (16%)	1 (25%)	10	0.14
2	0 (0%)	4 (13%)	2 (50%)	6	-
3	9 (50%)	12 (39%)	0 (0%)	21	-
4	5 (28%)	10 (32%)	1 (25%)	16	-

Interpretation

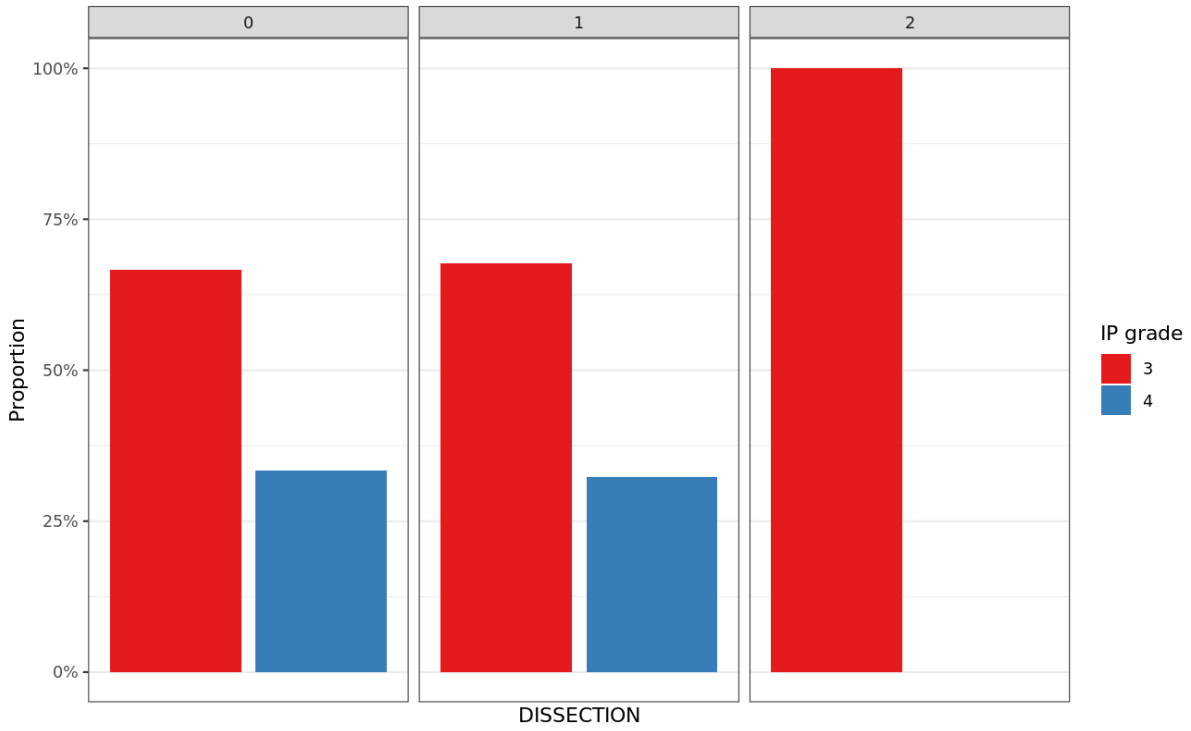
The distribution of FP grade is not significantly different depending on DISSECTION (p = 0.14).

Description of the IP grade

Distribution of IP grade according to GLASS



	3	4
IP grade	37 (70%)	16 (30%)



IP grade, n					
3	12 (67%)	21 (68%)	4 (100%)	37	0.53
4	6 (33%)	10 (32%)	0 (0%)	16	-

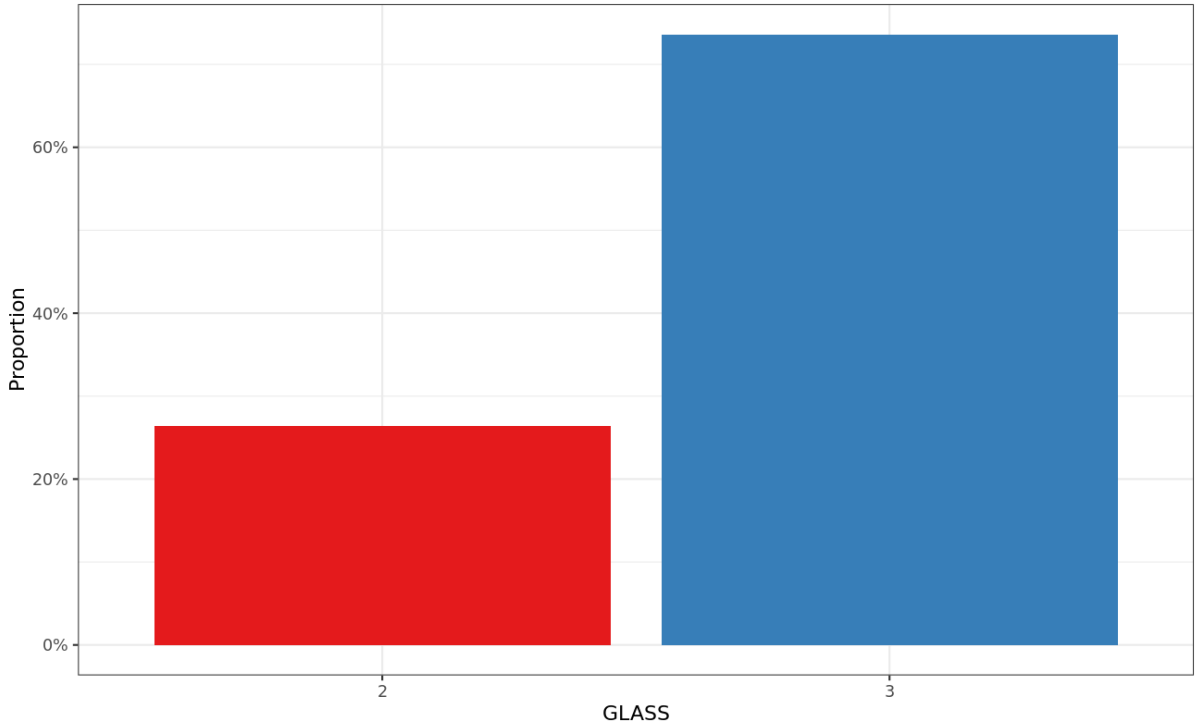
Interpretation

The distribution of IP grade is not significantly different depending on DISSECTION (p = 0.53).

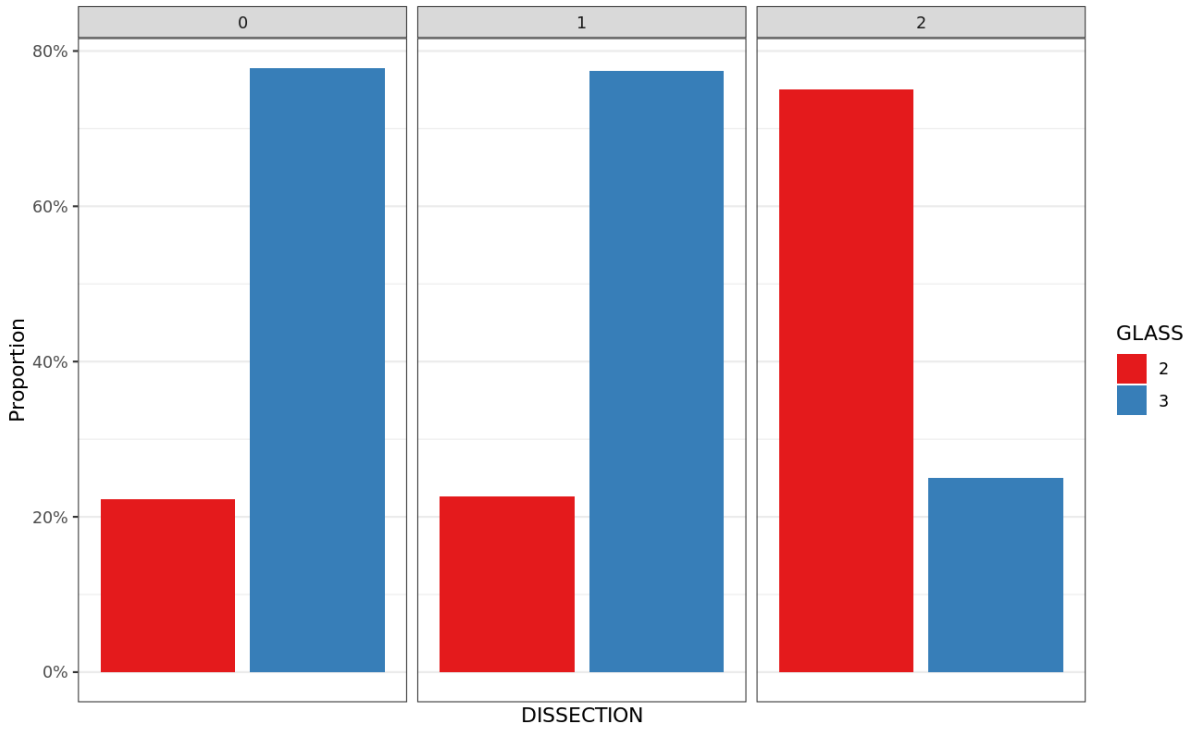
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the GLASS

Distribution of GLASS



	2	**3**
GLASS	14 (26%)	39 (74%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
GLASS, n					
2	4 (22%)	7 (23%)	3 (75%)	14	0.095
3	14 (78%)	24 (77%)	1 (25%)	39	-

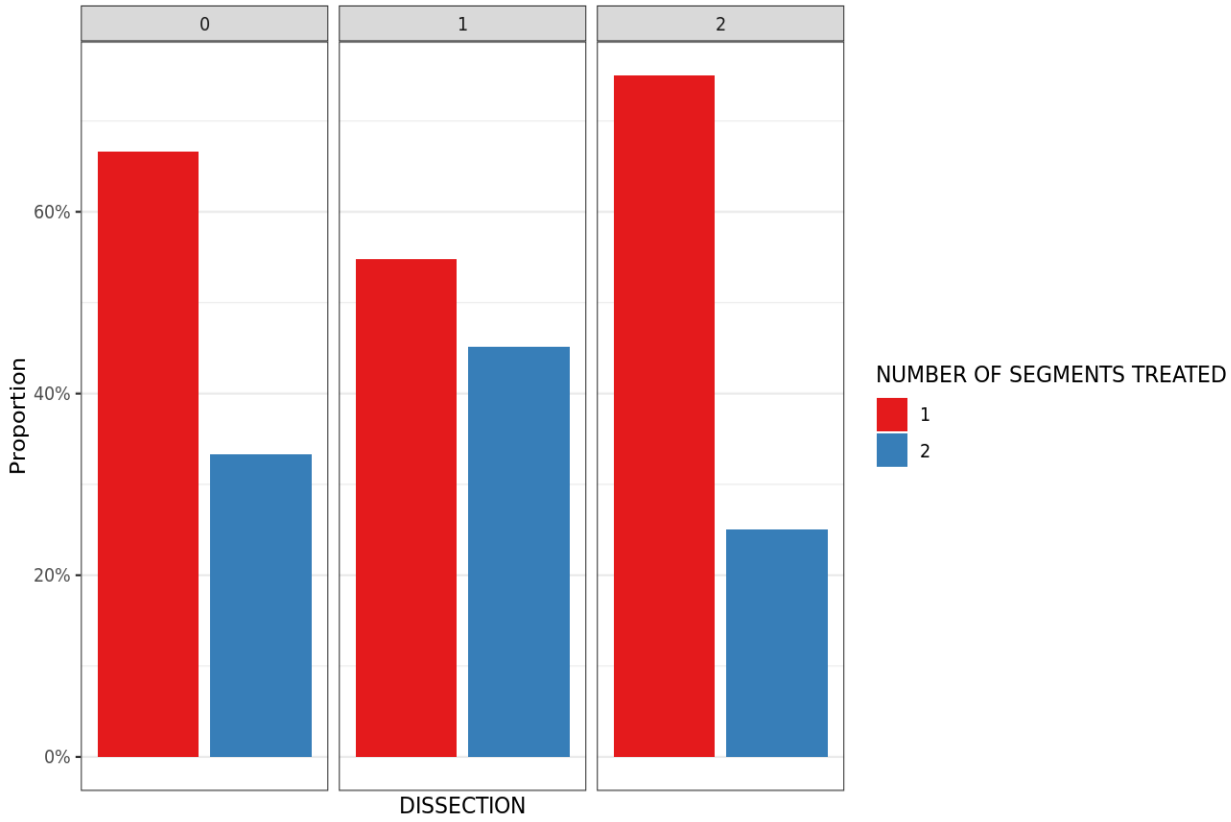
Interpretation

The distribution of GLASS is not significantly different depending on DISSECTION (p = 0.095).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the NUMBER OF SEGMENTS TREATED

Distribution of NUMBER OF SEGMENTS TREATED



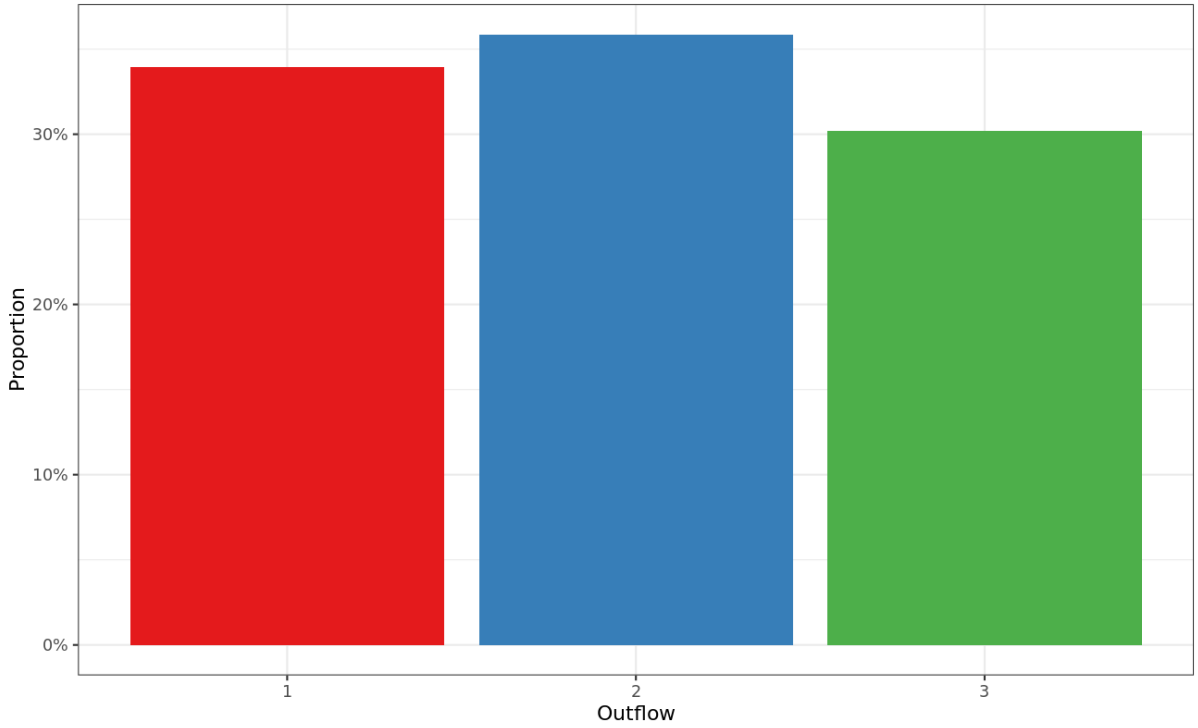
	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
NUMBER OF SEGMENTS TREATED, n					
1	12 (67%)	17 (55%)	3 (75%)	32	0.61
2	6 (33%)	14 (45%)	1 (25%)	21	-

Interpretation

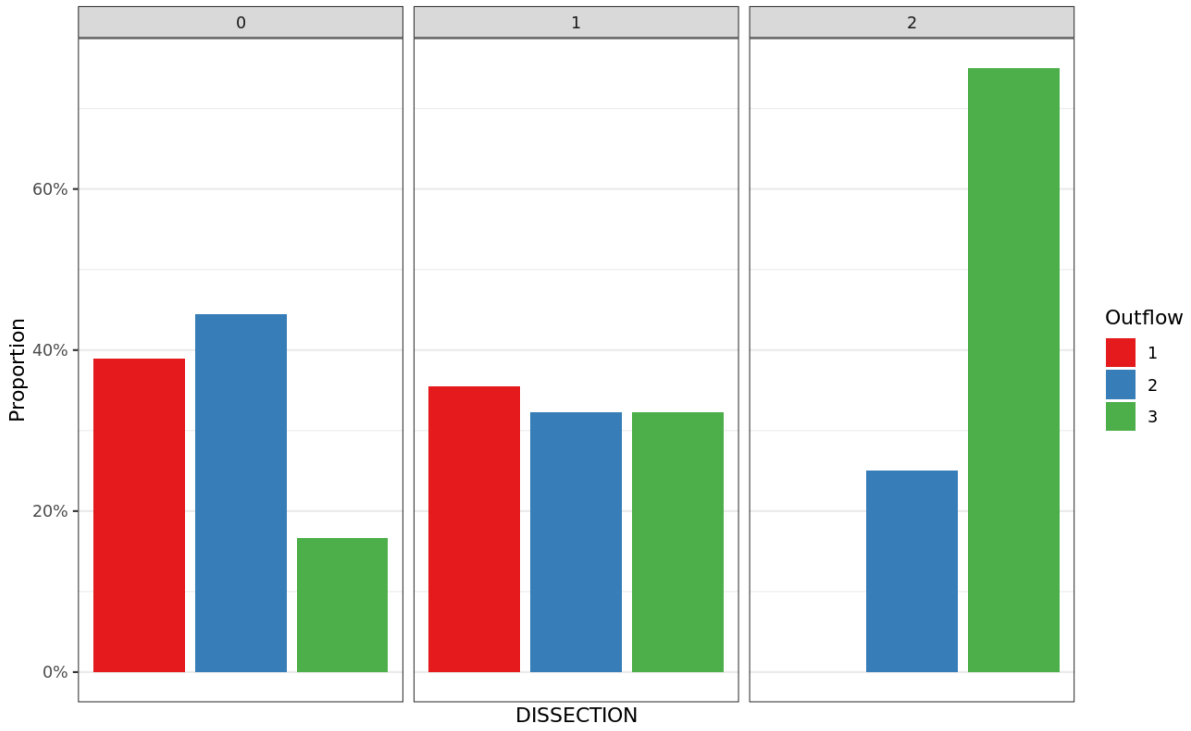
The distribution of NUMBER OF SEGMENTS TREATED is not significantly different depending on DISSECTION (p = 0.61).

Description of the number of Infrapopliteal Outflow vessels

Distribution of Outflow



	1	2	3
Outflow	18 (34%)	19 (36%)	16 (30%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
Outflow, n					
1	7 (39%)	11 (35%)	0 (0%)	18	0.24
2	8 (44%)	10 (32%)	1 (25%)	19	-
3	3 (17%)	10 (32%)	3 (75%)	16	-

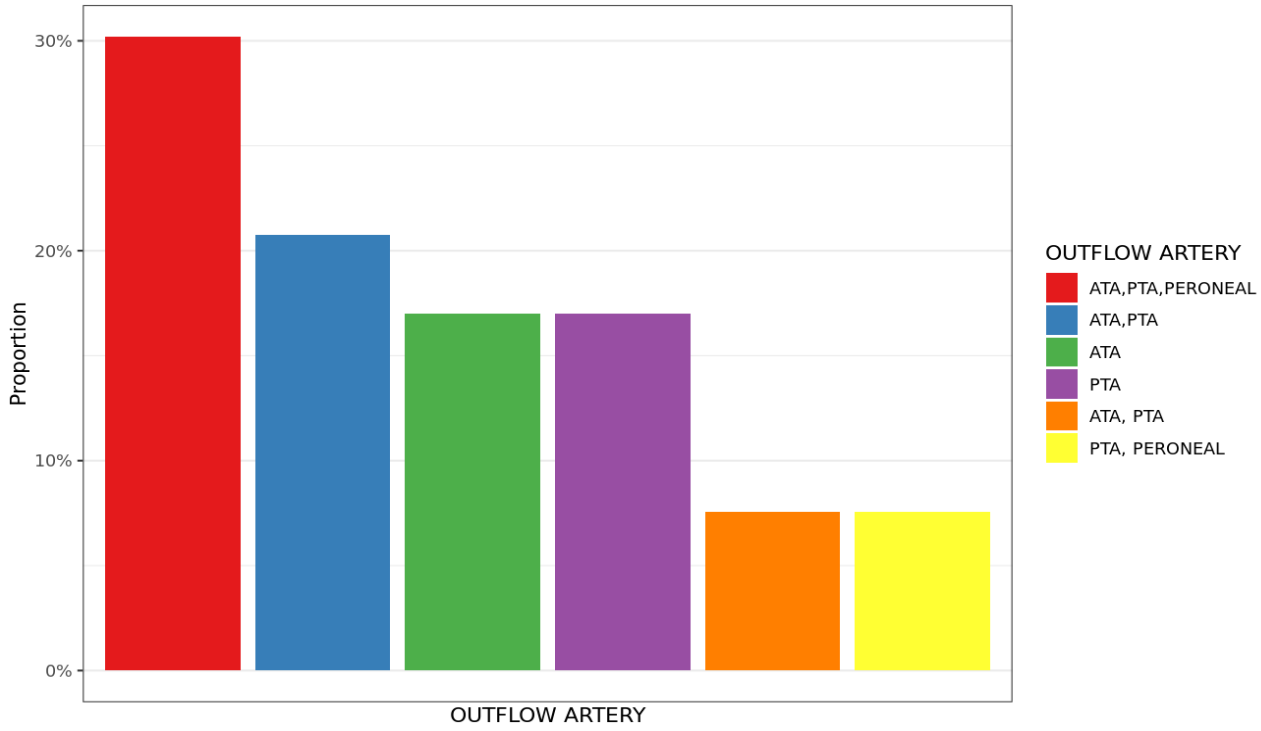
Interpretation

The distribution of Outflow is not significantly different depending on DISSECTION (p = 0.24).

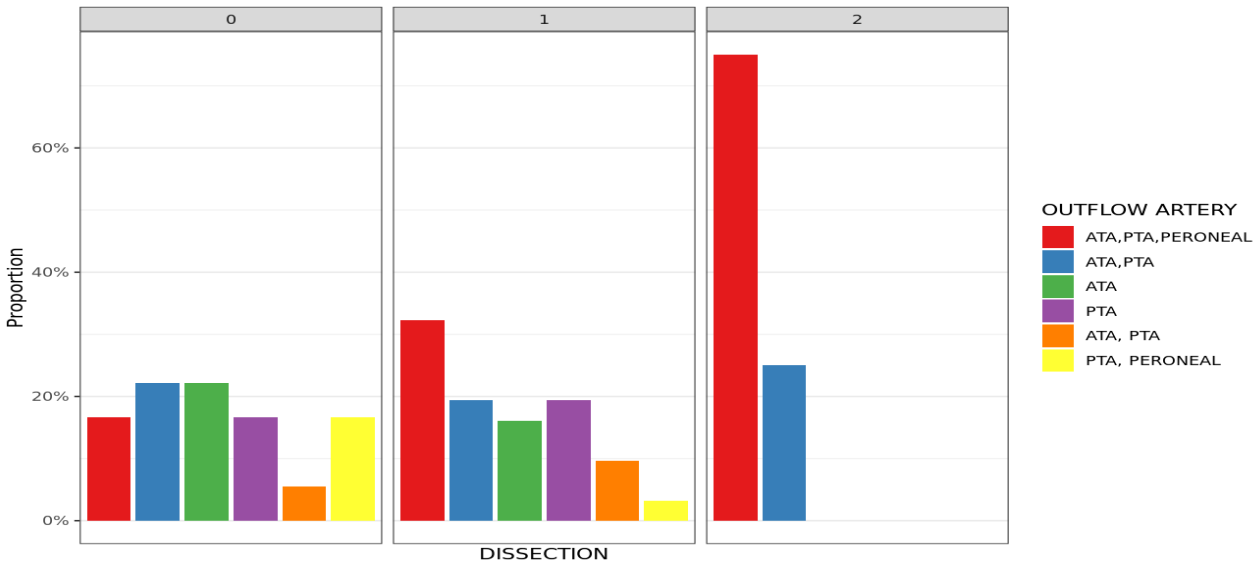
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the OUTFLOW ARTERY

Distribution of OUTFLOW ARTERY



	ATA, PTA ,PERONEAL	ATA,PTA	ATA	PTA	ATA, PTA	PTA, PERONEAL
OUTFLOW ARTERY	16 (30%)	11 (21%)	9 (17%)	9 (17%)	4 (7.5%)	4 (7.5%)



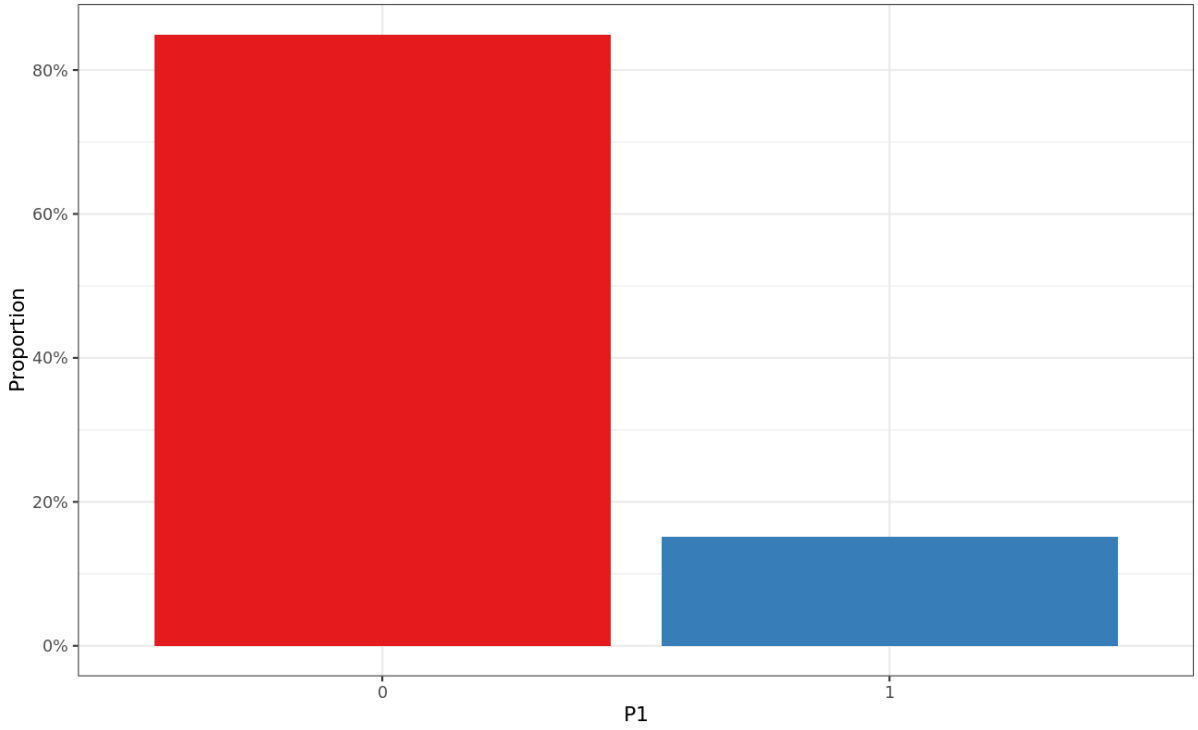
	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
OUTFLOW ARTERY, n					
ATA,PTA,PERONEAL	3 (17%)	10 (32%)	3 (75%)	16	0.66
ATA,PTA	4 (22%)	6 (19%)	1 (25%)	11	-
ATA	4 (22%)	5 (16%)	0 (0%)	9	-
PTA	3 (17%)	6 (19%)	0 (0%)	9	-
ATA, PTA	1 (5.6%)	3 (9.7%)	0 (0%)	4	-
PTA, PERONEAL	3 (17%)	1 (3.2%)	0 (0%)	4	-

Interpretation

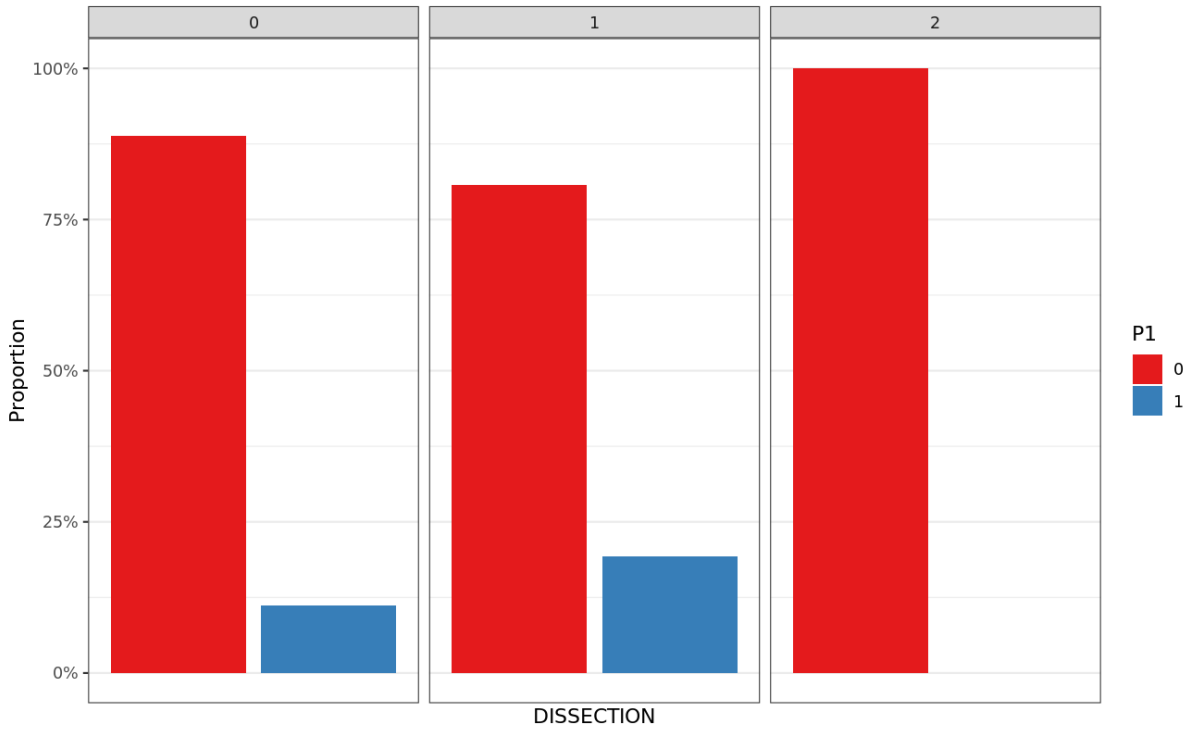
The distribution of OUTFLOW ARTERY is not significantly different depending on DISSECTION (p = 0.66).

Description of the P1[POPLITEAL] segment

Distribution of P1



	0[NO DISSECTION]	1[DISSECTION]
P1	45 (85%)	8 (15%)



Save this figure

	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
P1, n					
0	16 (89%)	25 (81%)	4 (100%)	45	0.85
1	2 (11%)	6 (19%)	0 (0%)	8	-

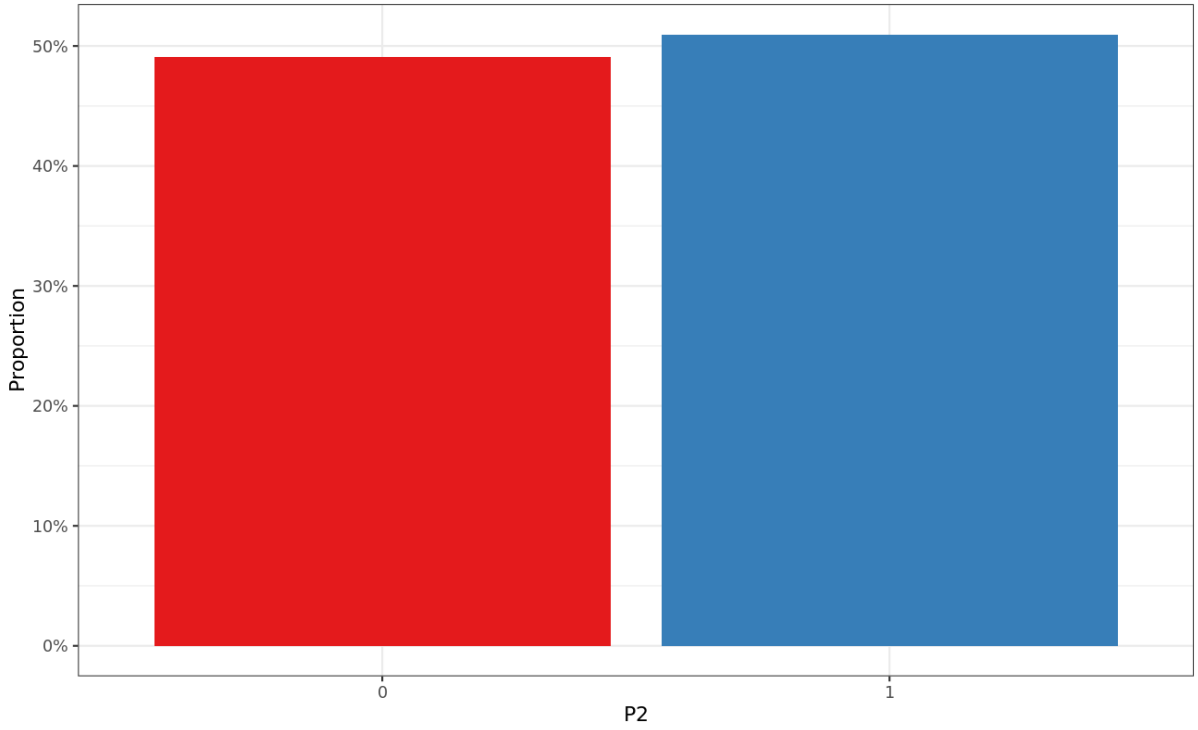
Interpretation

The distribution of P1 is not significantly different depending on DISSECTION (p = 0.85).

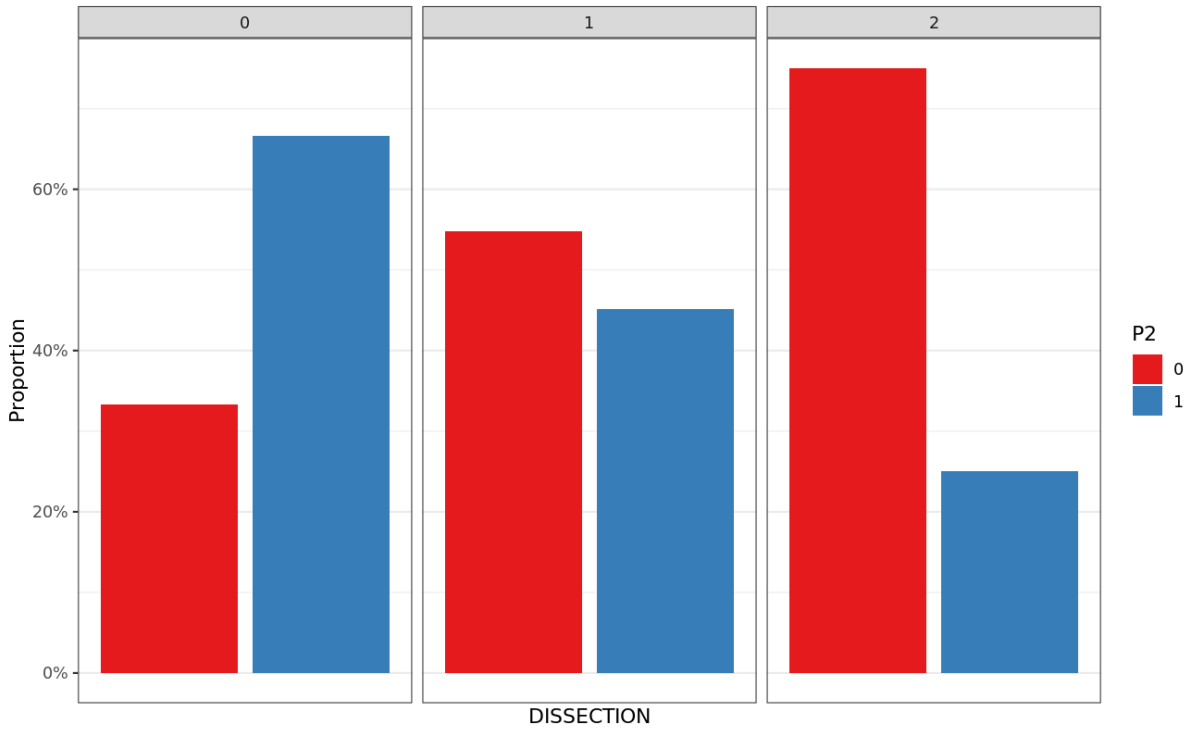
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the P2 segment

Distribution of P2



	0[NO DISSECTION]	1[DISSECTION]
P2	26 (49%)	27 (51%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
P2, n					
0	6 (33%)	17 (55%)	3 (75%)	26	0.23
1	12 (67%)	14 (45%)	1 (25%)	27	-

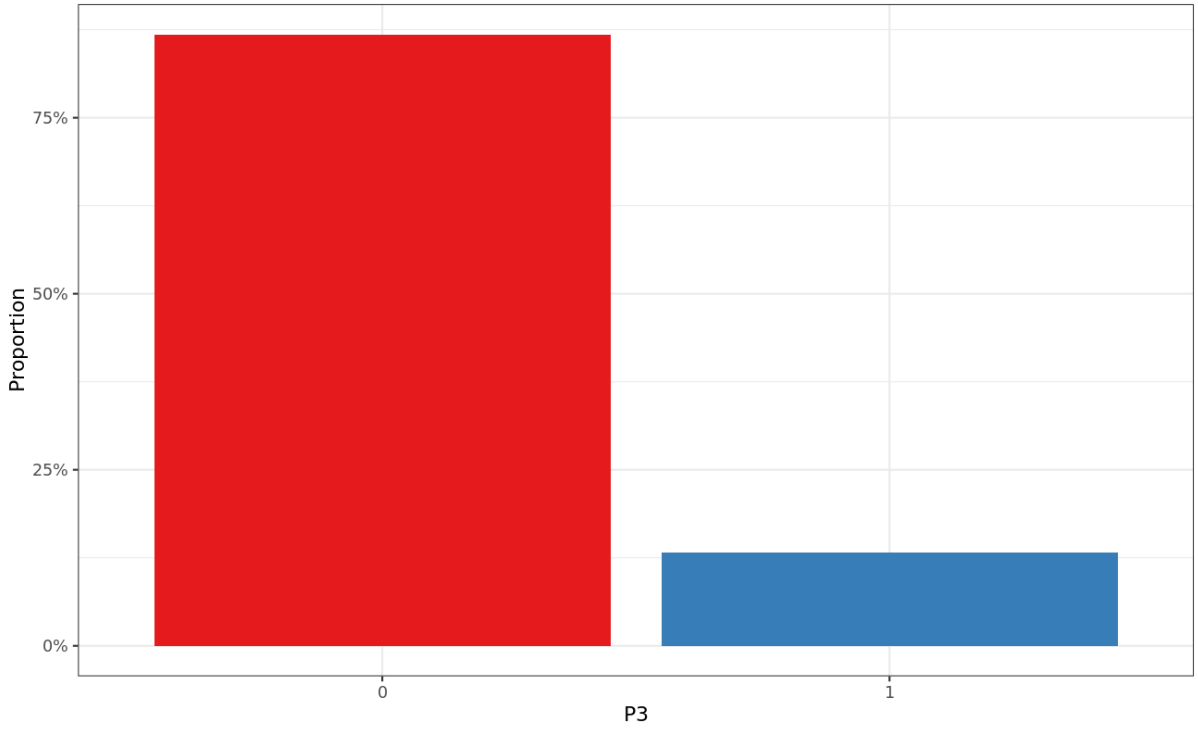
Interpretation

The distribution of P2 is not significantly different depending on DISSECTION (p = 0.23).

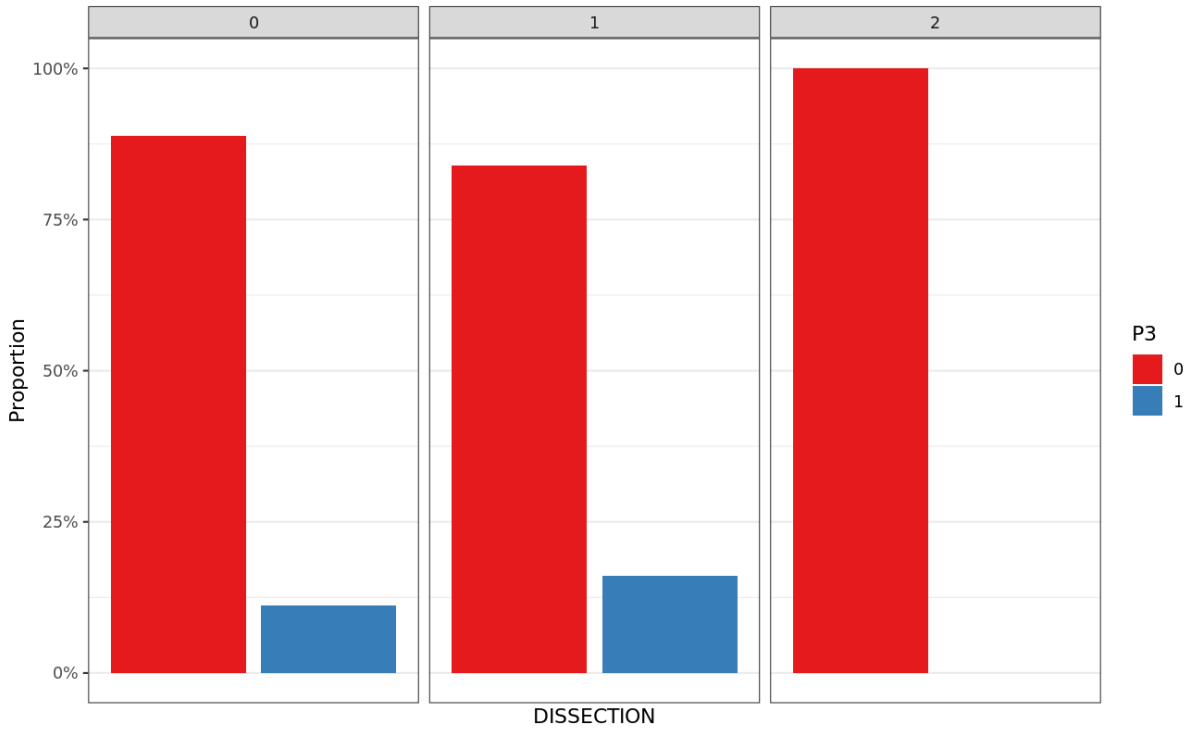
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed

Description of the P3 segment

Distribution of P3



	0[NO DISSECTION]	1[DISSECTION]
P3	46 (87%)	7 (13%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
P3, n					
0	16 (89%)	26 (84%)	4 (100%)	46	1
1	2 (11%)	5 (16%)	0 (0%)	7	-

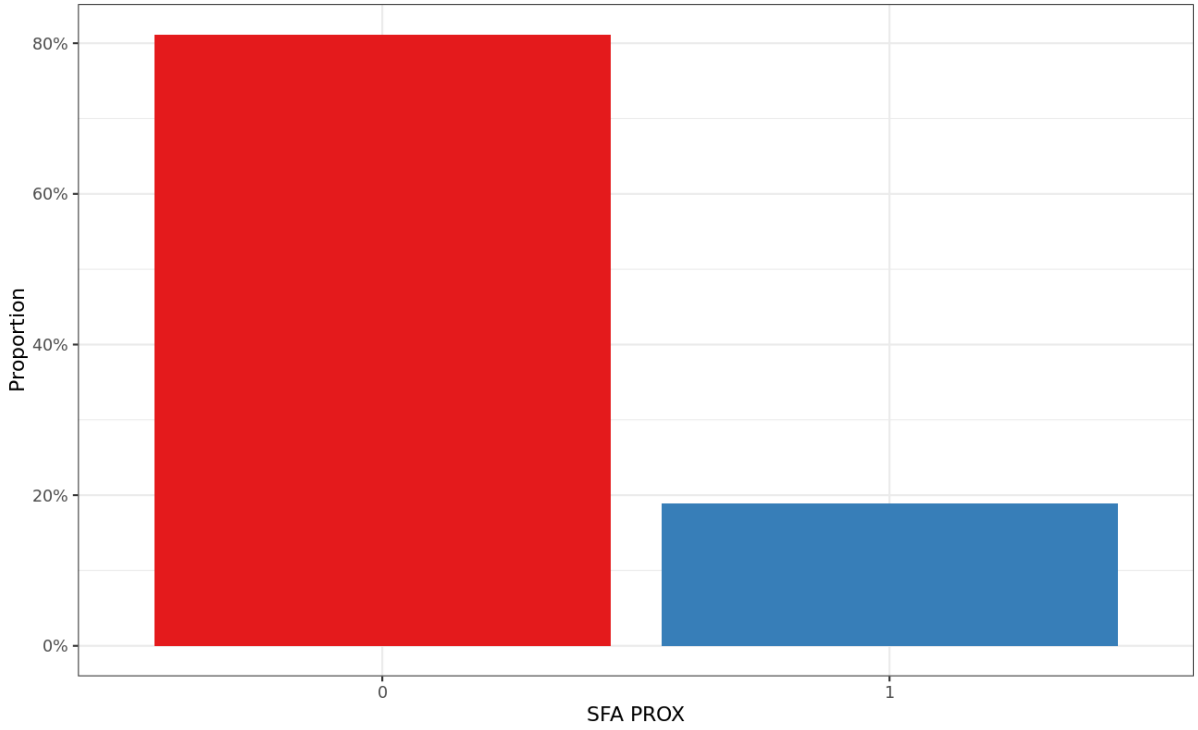
Interpretation

The distribution of P3 is not significantly different depending on DISSECTION (p = 1).

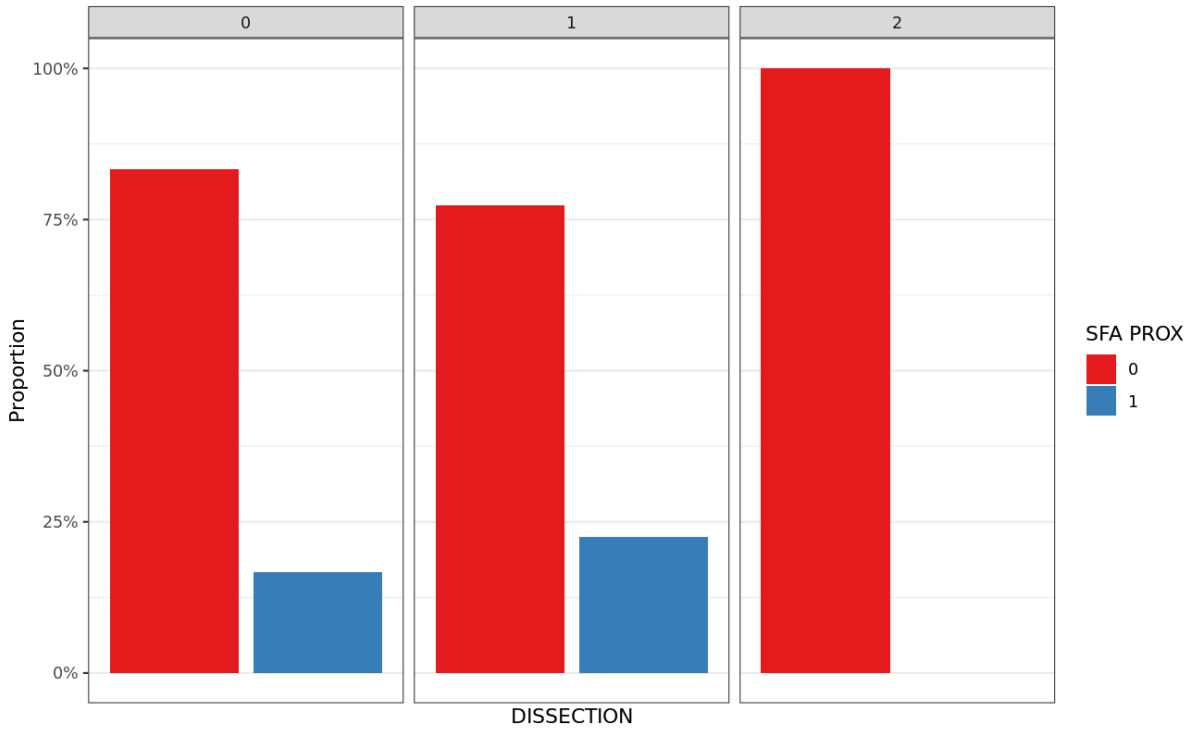
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the SFA PROXIMAL segment

Distribution of SFA PROX



	0[NO DISSECTION]	1[DISSECTION]
SFA PROX	43 (81%)	10 (19%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
SFA PROX, n					
0	15 (83%)	24 (77%)	4 (100%)	43	0.76
1	3 (17%)	7 (23%)	0 (0%)	10	-

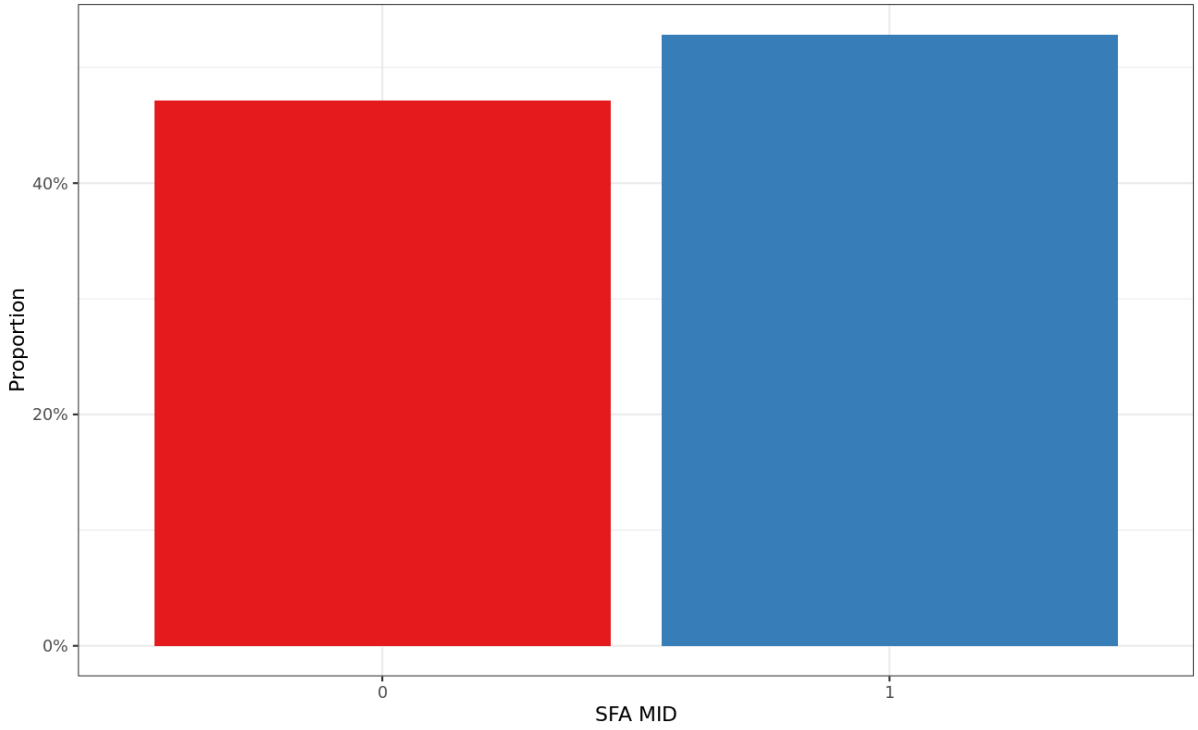
Interpretation

The distribution of SFA PROX is not significantly different depending on DISSECTION (p = 0.76).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

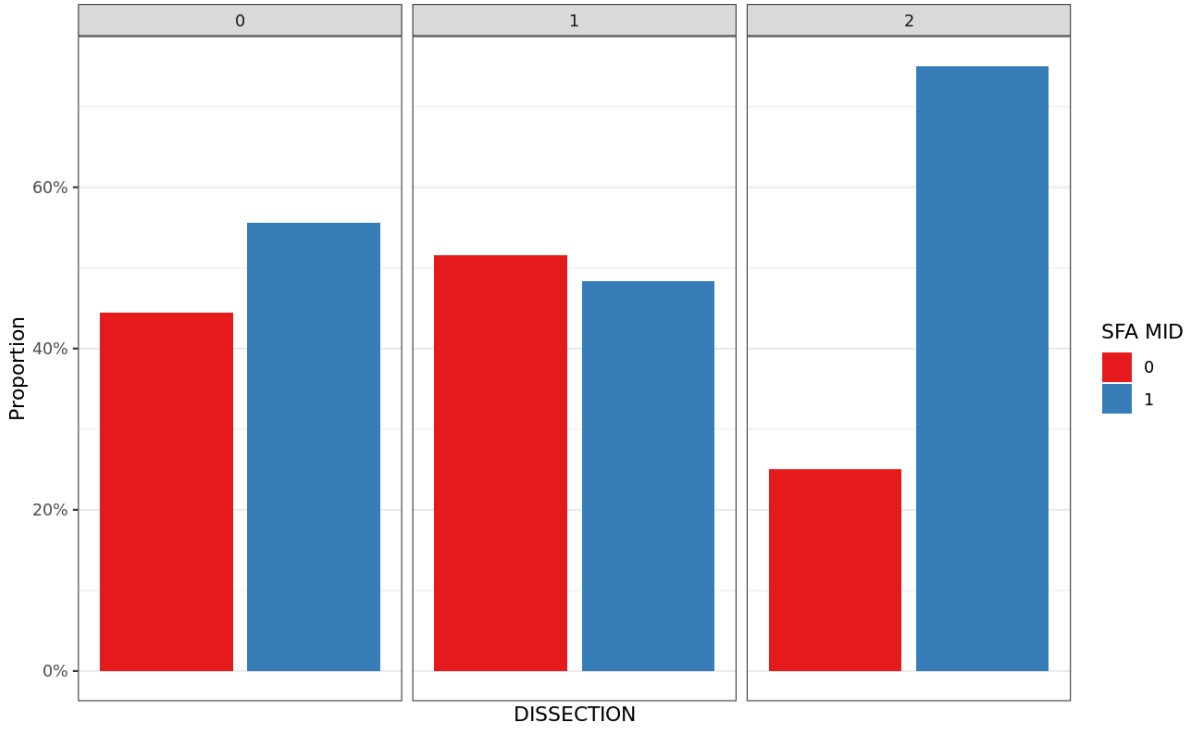
Description of the SFA MID segment

Distribution of SFA MID



	0[NO DISSECTION]	1[DISSECTION]
SFA MID	25 (47%)	28 (53%)

SFA MID depending on DISSECTION



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
SFA MID, n					
0	8 (44%)	16 (52%)	1 (25%)	25	0.64
1	10 (56%)	15 (48%)	3 (75%)	28	-

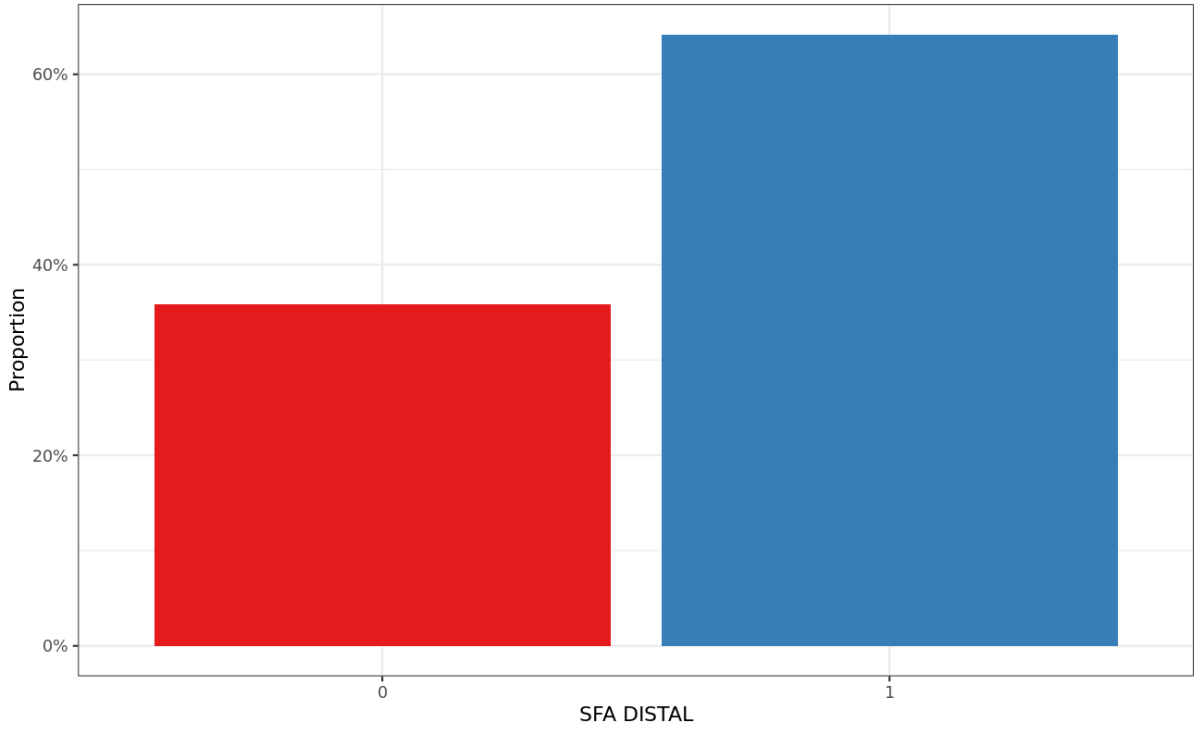
Interpretation

The distribution of SFA MID is not significantly different depending on DISSECTION (p = 0.64).

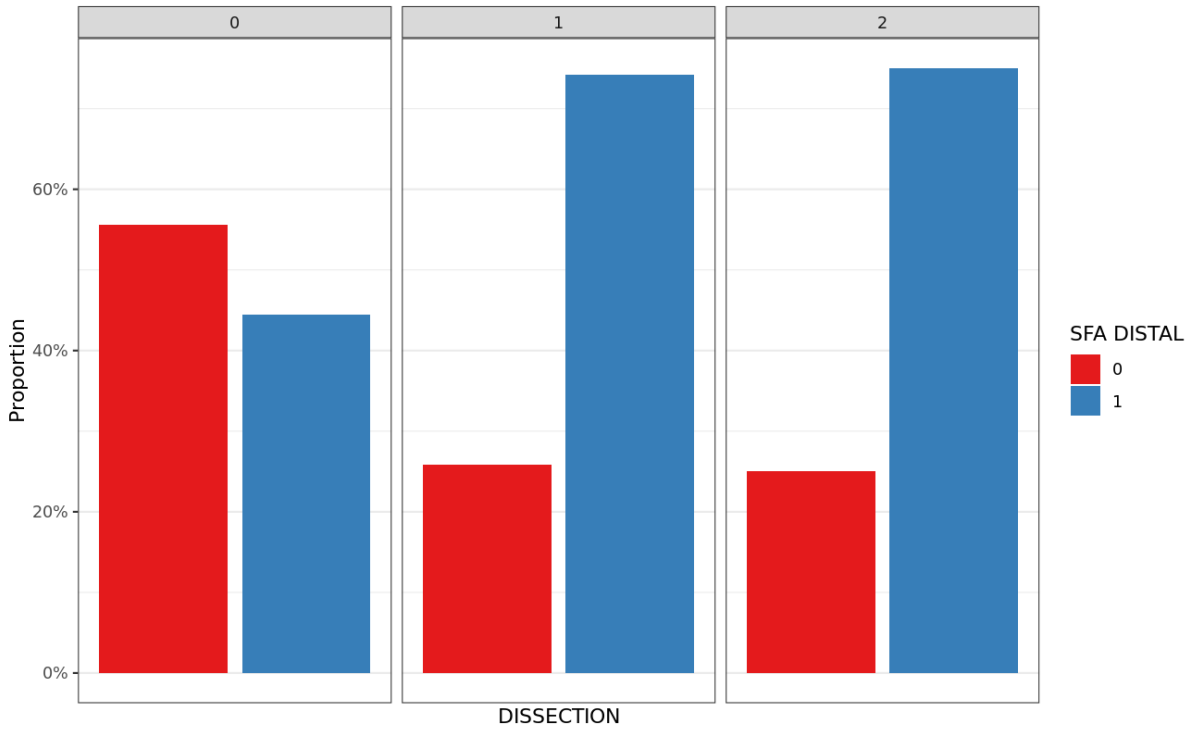
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the SFA DISTAL segment

Distribution of SFA DISTAL



	0[NO DISSECTION]	1[DISSECTION]
SFA DISTAL	19 (36%)	34 (64%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
SFA DISTAL, n					
0	10 (56%)	8 (26%)	1 (25%)	19	0.1
1	8 (44%)	23 (74%)	3 (75%)	34	-

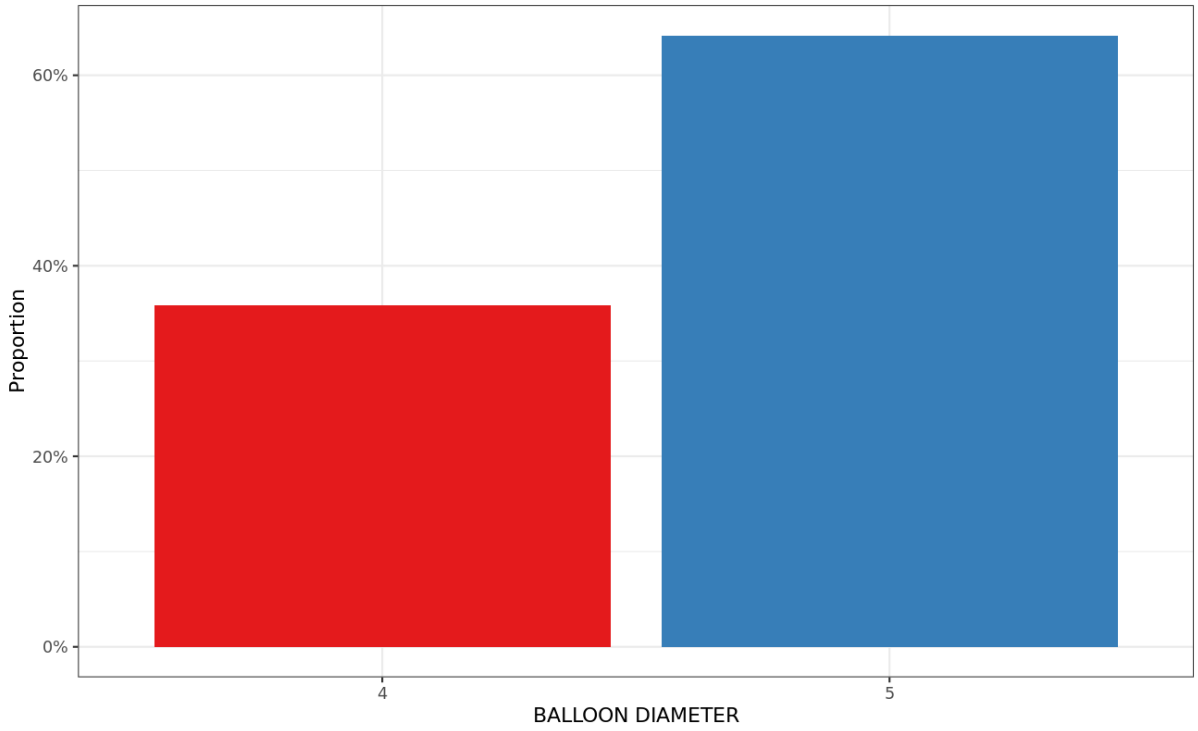
Interpretation

The distribution of SFA DISTAL is not significantly different depending on DISSECTION (p = 0.1).

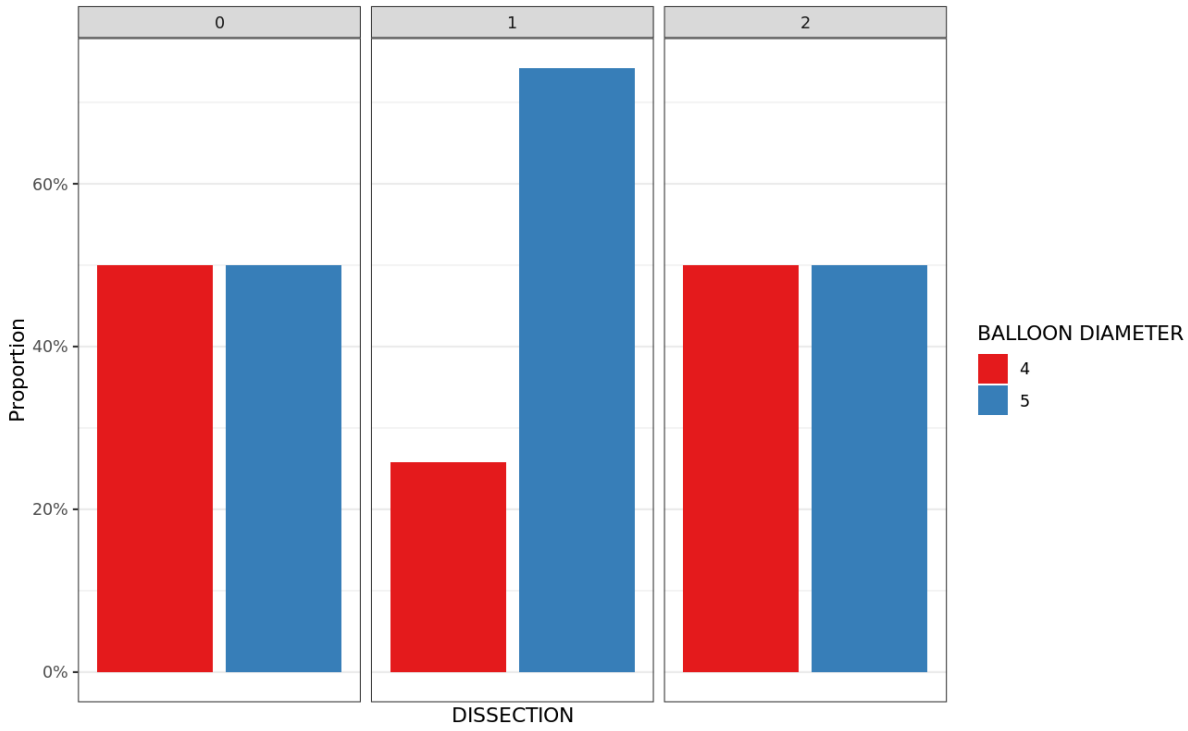
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the BALLOON DIAMETER

Distribution of BALLOON DIAMETER



	4mm	5mm
BALLOON DIAMETER	19 (36%)	34 (64%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
BALLOON DIAMETER, n					
4mm	9 (50%)	8 (26%)	2 (50%)	19	0.17
5mm	9 (50%)	23 (74%)	2 (50%)	34	-

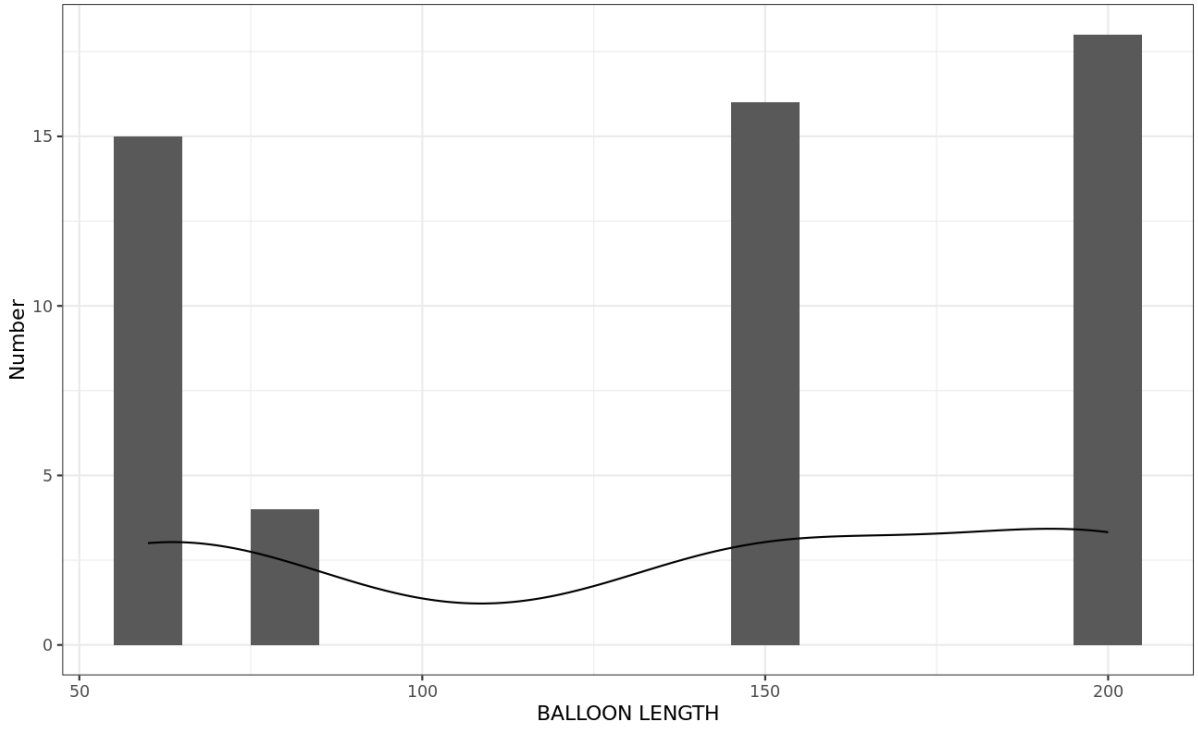
Interpretation

The distribution of BALLOON DIAMETER is not significantly different depending on DISSECTION (p = 0.17).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

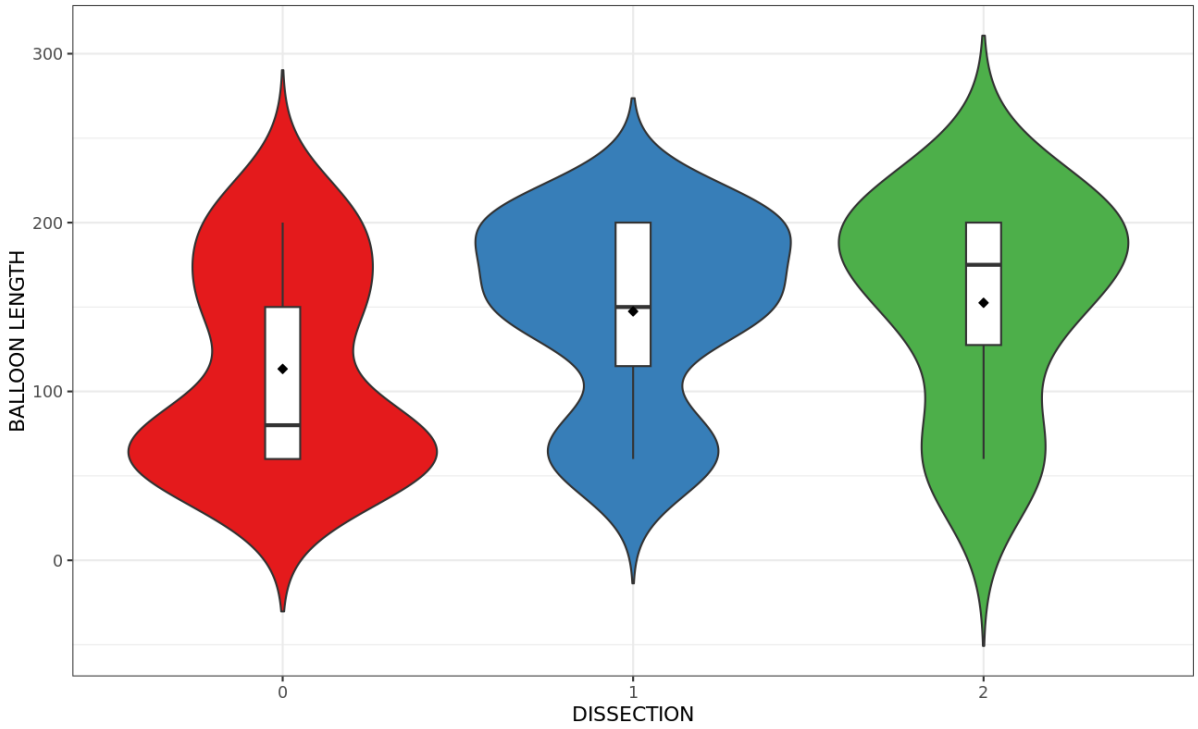
Description of the BALLOON LENGTH

BALLOON LENGTH distribution



	mean (SD)	median [Q25-75]	min	max	n
BALLOON LENGTH	136 (58.2)	150 [60.0; 200]	60.0	200	53

Description of the distribution of BALLOON LENGTH depending on DISSECTION



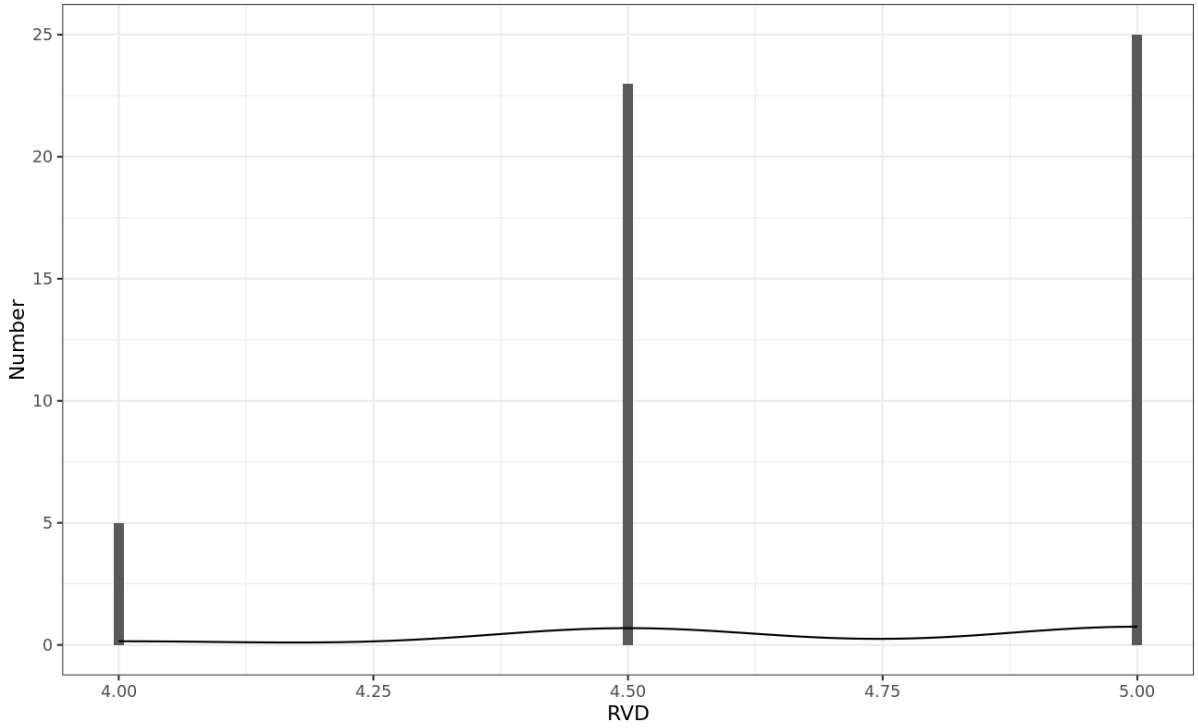
	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
BALLOON LENGTH, median [Q25-75]	80.0 [60.0; 150]	150 [115; 200]	175 [128; 200]	53	0.15

Interpretation

As the numbers of subjects compared were small, a non-parametric test was carried out (Kruskal-Wallis test). The exact interpretation is that the average rank of BALLOON LENGTH is not significantly different depending on DISSECTION (p = 0.15).

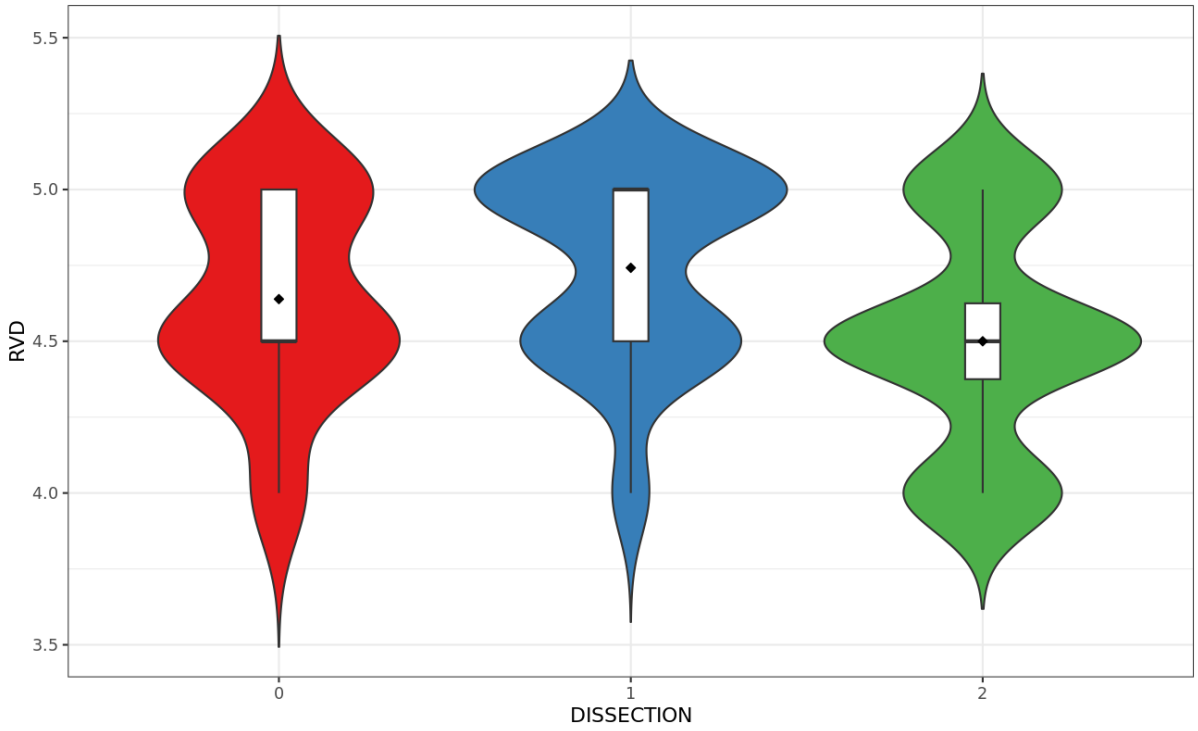
Description of the reference vessel RVD

RVD distribution



	mean (SD)	median [Q25-75]	min	max	n
RVD	4.69 (0.329)	4.50 [4.50; 5.00]	4.00	5.00	53

Description of the distribution of RVD depending on DISSECTION



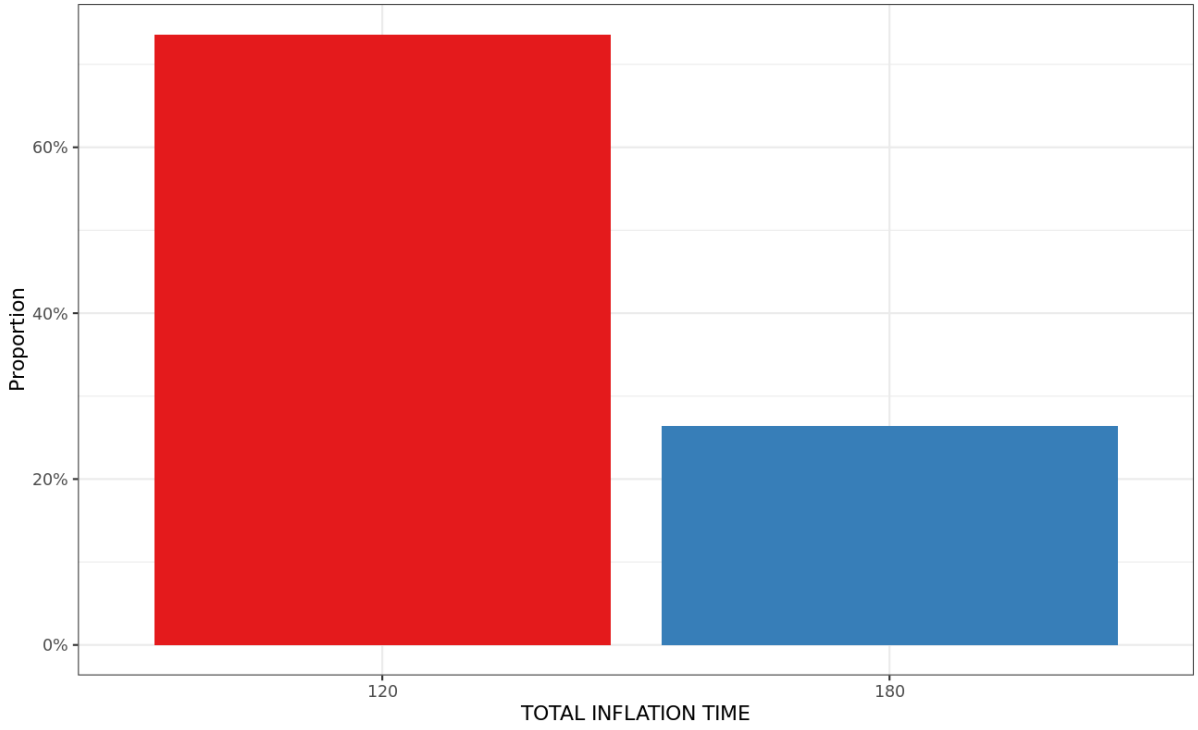
	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
RVD, median [Q25-75]	4.50 [4.50; 5.00]	5.00 [4.50; 5.00]	4.50 [4.38; 4.62]	53	0.3

Interpretation

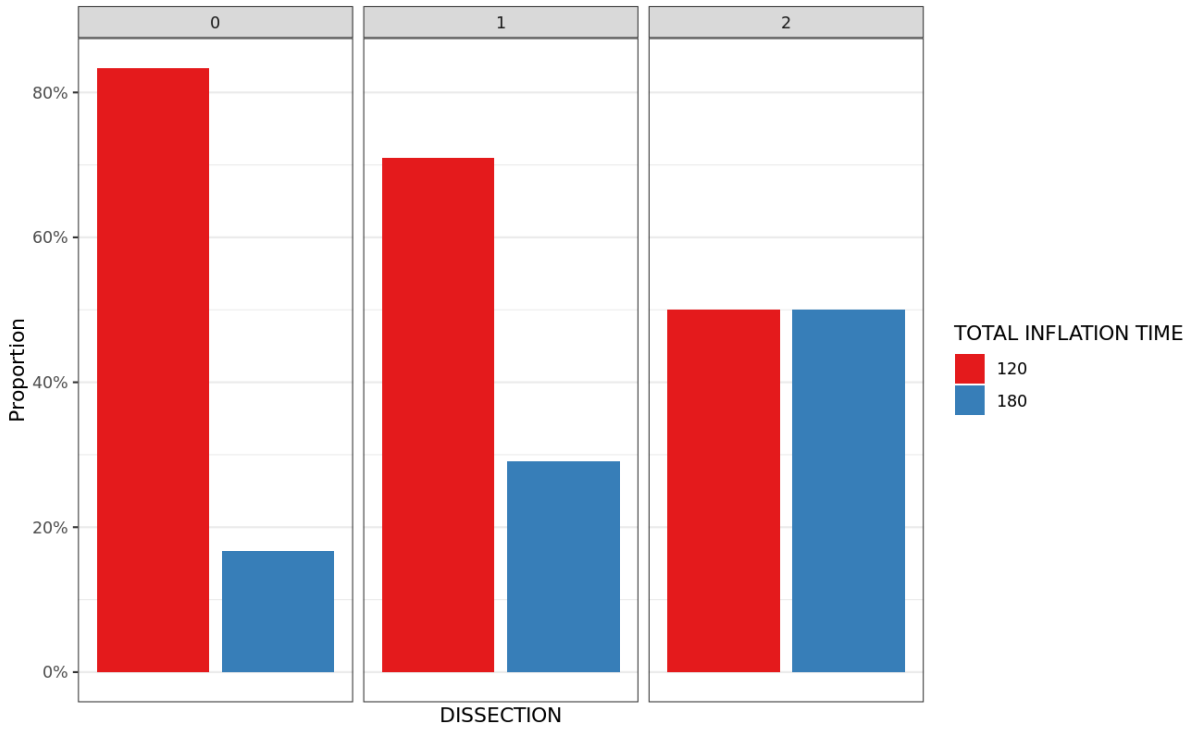
As the numbers of subjects compared were small, a non-parametric test was carried out (Kruskal-Wallis test). The exact interpretation is that the average rank of RVD is not significantly different depending on DISSECTION (p = 0.3).

Description of the TOTAL INFLATION TIME

Distribution of TOTAL INFLATION TIME by class



	120sec	**180sec**
TOTAL INFLATION TIME	39 (74%)	14 (26%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
TOTAL INFLATION TIME, n					
120sec	15 (83%)	22 (71%)	2 (50%)	39	0.34
180sec	3 (17%)	9 (29%)	2 (50%)	14	-

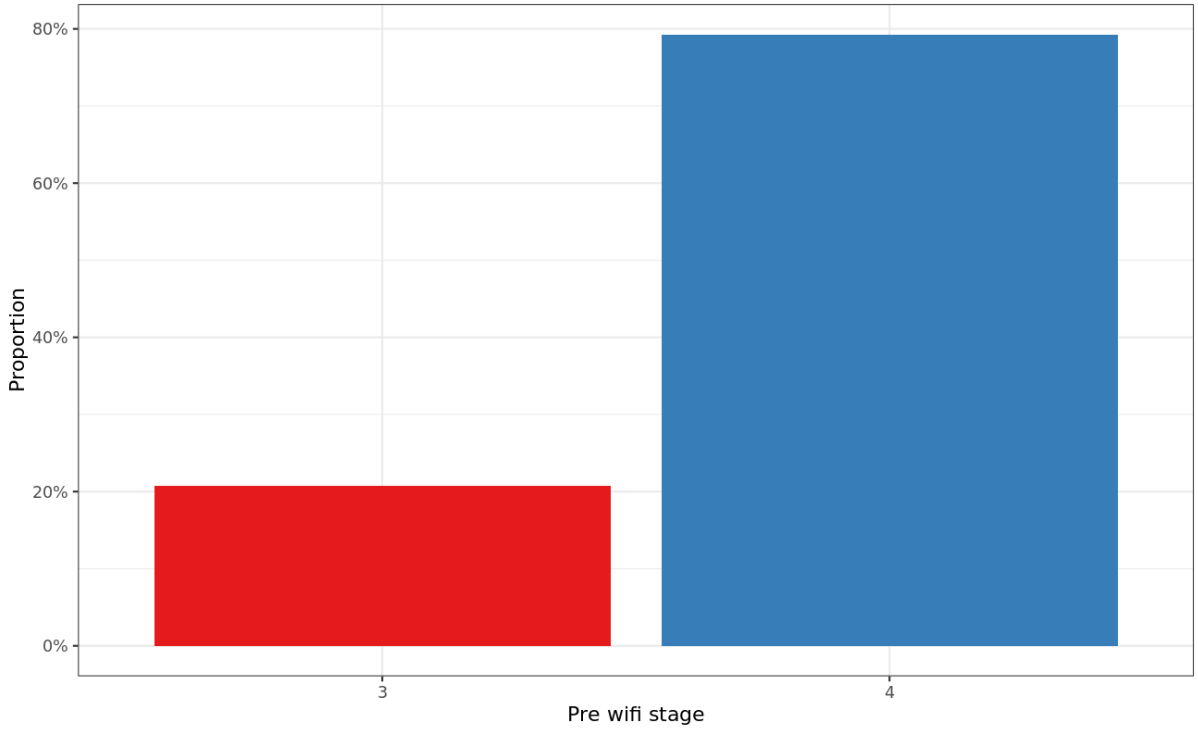
Interpretation

The distribution of TOTAL INFLATION TIME is not significantly different depending on DISSECTION (p = 0.34).

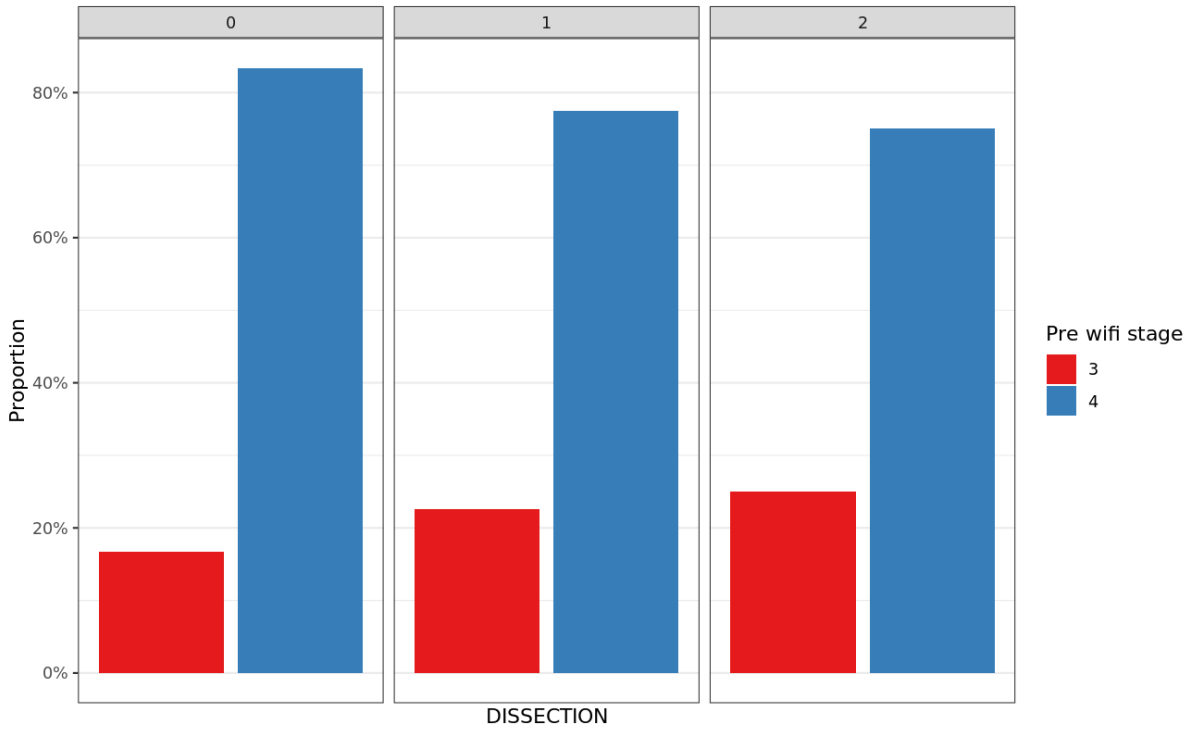
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the Pre WIFI stage

Distribution of Pre WIFI stage by class



	3rd stage	**4th stage**
Pre WIFI stage	11 (21%)	42 (79%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
Pre WIFI stage, n					
3	3 (17%)	7 (23%)	1 (25%)	11	0.88
4	15 (83%)	24 (77%)	3 (75%)	42	-

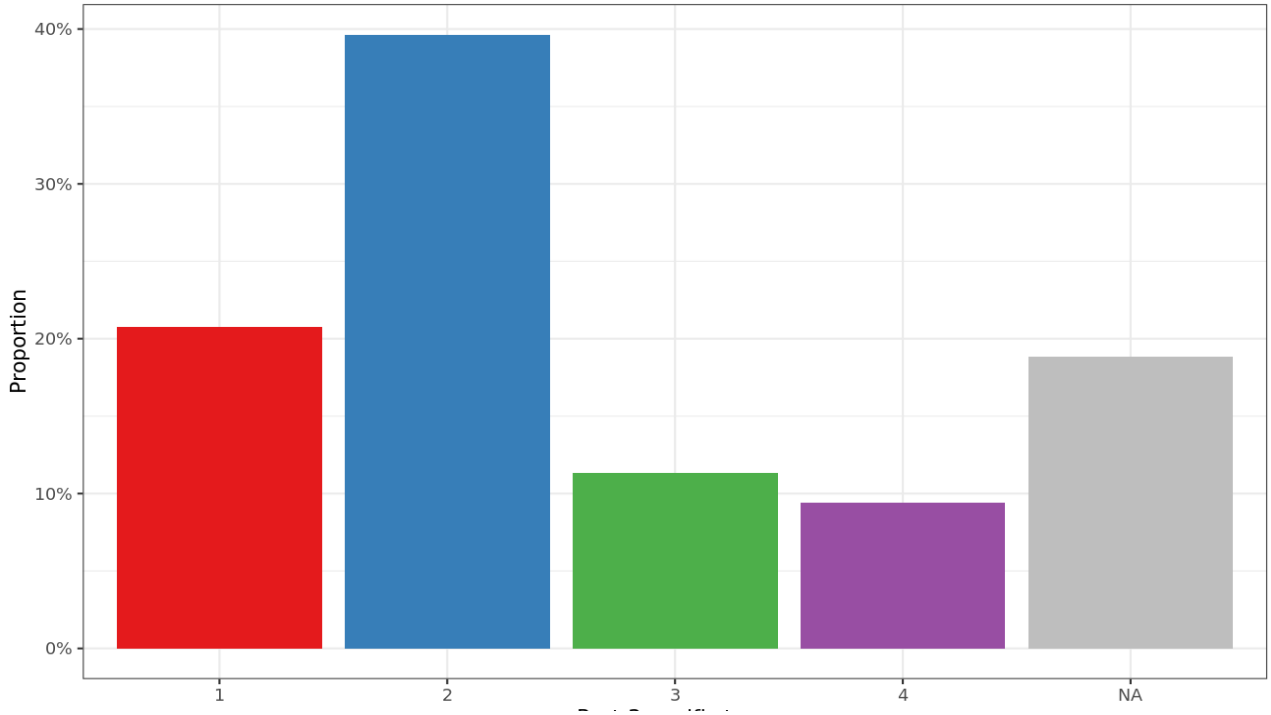
Interpretation

The distribution of Pre WIFI stage is not significantly different depending on DISSECTION (p = 0.88).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the Post 6m WIFI stage

Distribution of Post 6m WIFI stage by class



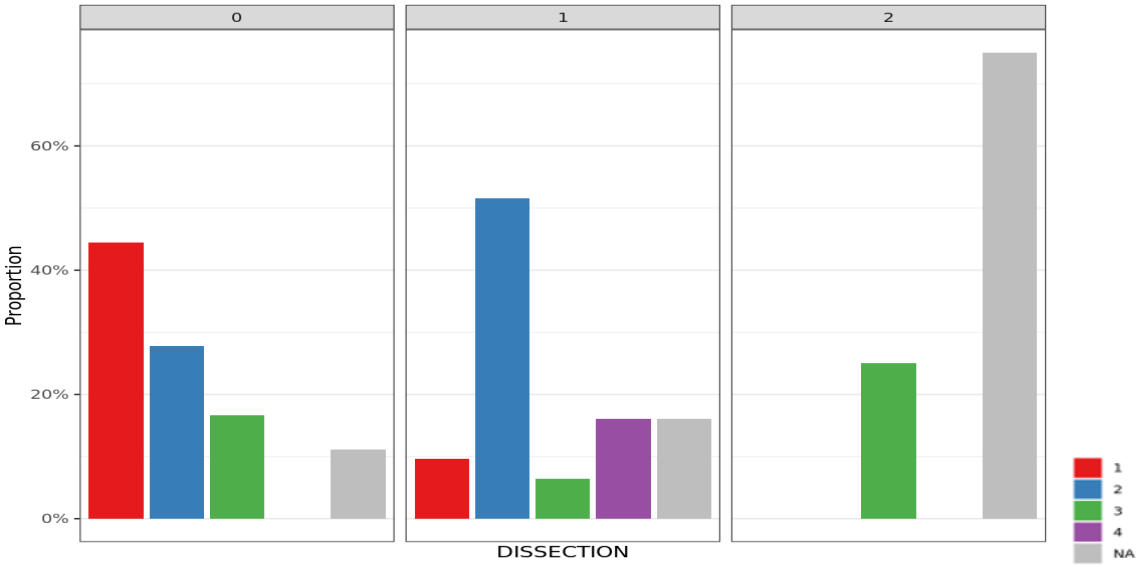
STAGE	1	2	3	4
Post 6m WIFI stage	11 (26%)	21 (49%)	6 (14%)	5 (12%)

This variable contains 10 missing values, i.e. 19% of the total.

Change in the order of the bars

Merge the classes

post 6m WIFI stage depending on DISSECTION



	DISSECTION 0 (n = 16)	DISSECTION 1 (n = 26)	DISSECTION 2 (n = 1)	n	p
Post 6m WIFI stage, n					
1	8 (50%)	3 (12%)	0 (0%)	11	**<0.01**
2	5 (31%)	16 (62%)	0 (0%)	21	-
3	3 (19%)	2 (7.7%)	1 (100%)	6	-
4	0 (0%)	5 (19%)	0 (0%)	5	-

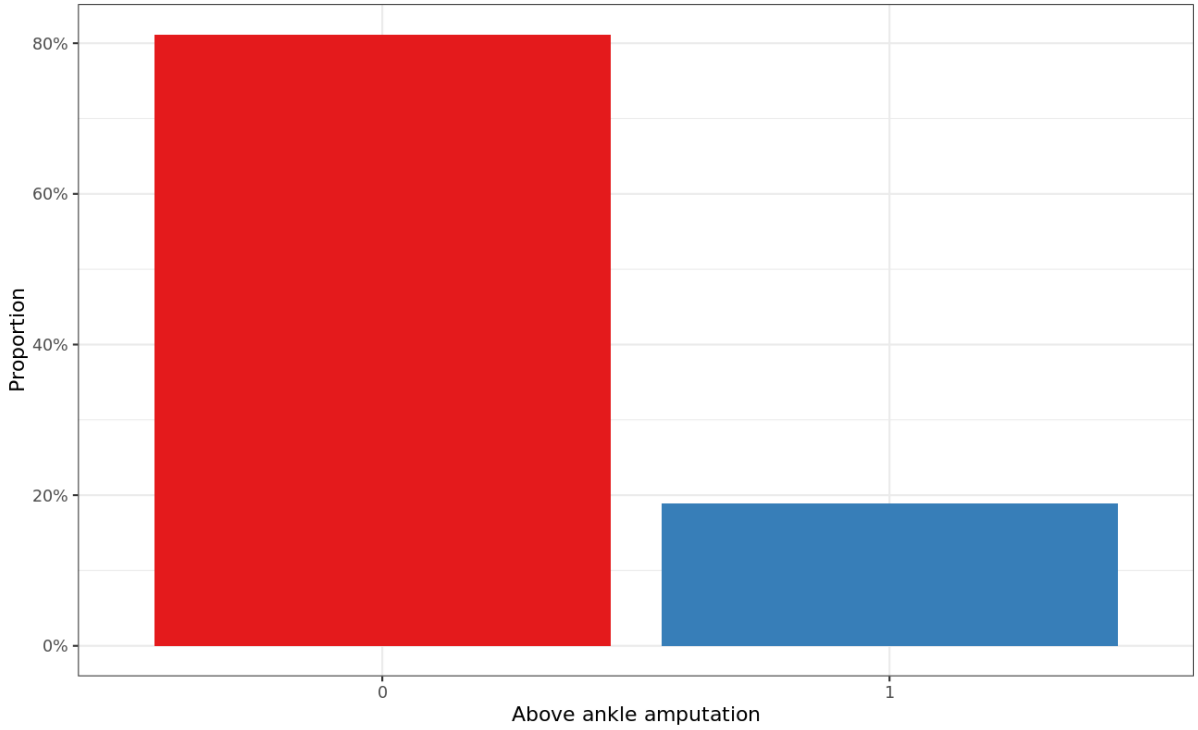
Interpretation

The distribution of Post 6m WIFI stage is significantly different depending on DISSECTION (p = **<0.01**).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

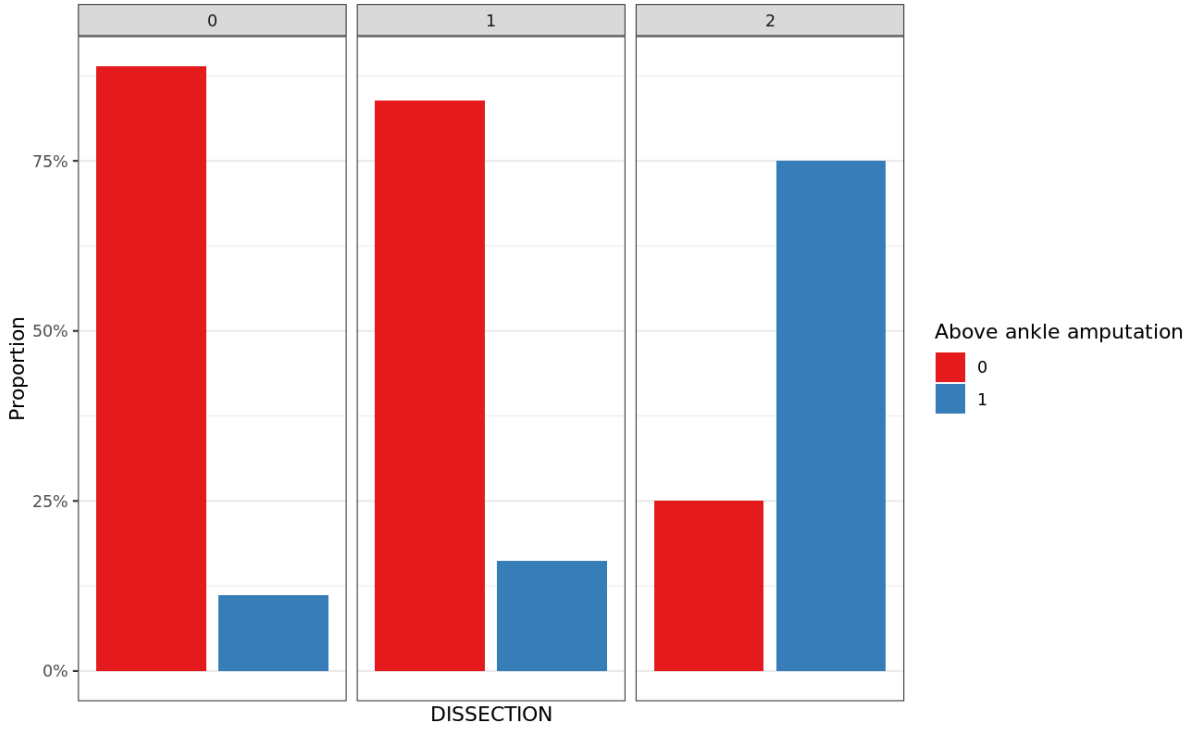
Description of the Above ankle amputation

Distribution of Above ankle amputation by class



	0[NO DISSECTION]	1[DISSECTION]
Above ankle amputation	43 (81%)	10 (19%)

Above ankle amputation depending on DISSECTION



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
Above ankle amputation, n					
0[NO]	16 (89%)	26 (84%)	1 (25%)	43	**0.035**
1[YES]	2 (11%)	5 (16%)	3 (75%)	10	-

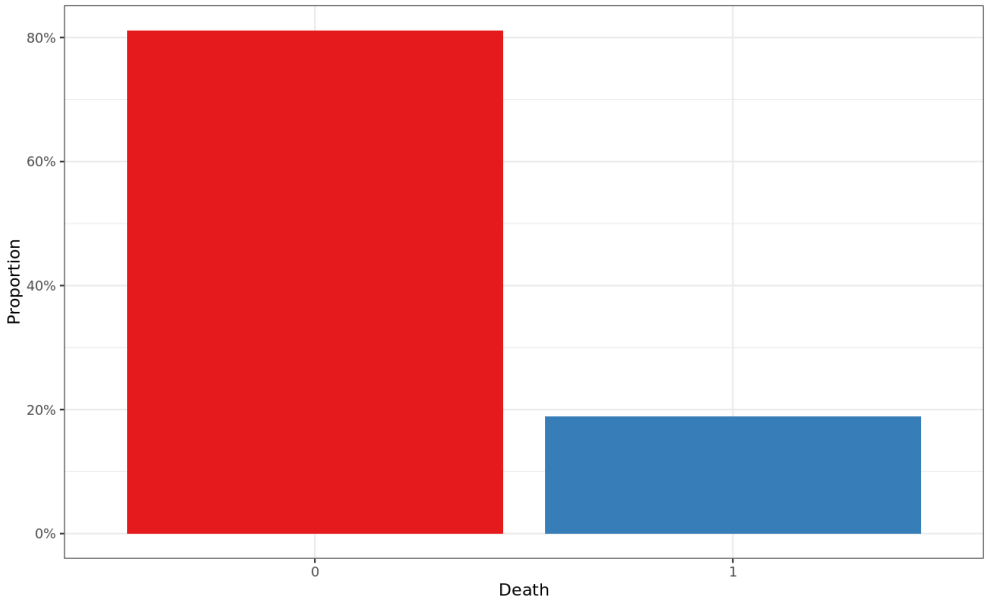
Interpretation

The distribution of Above ankle amputation is significantly different depending on DISSECTION (p = **0.035**).

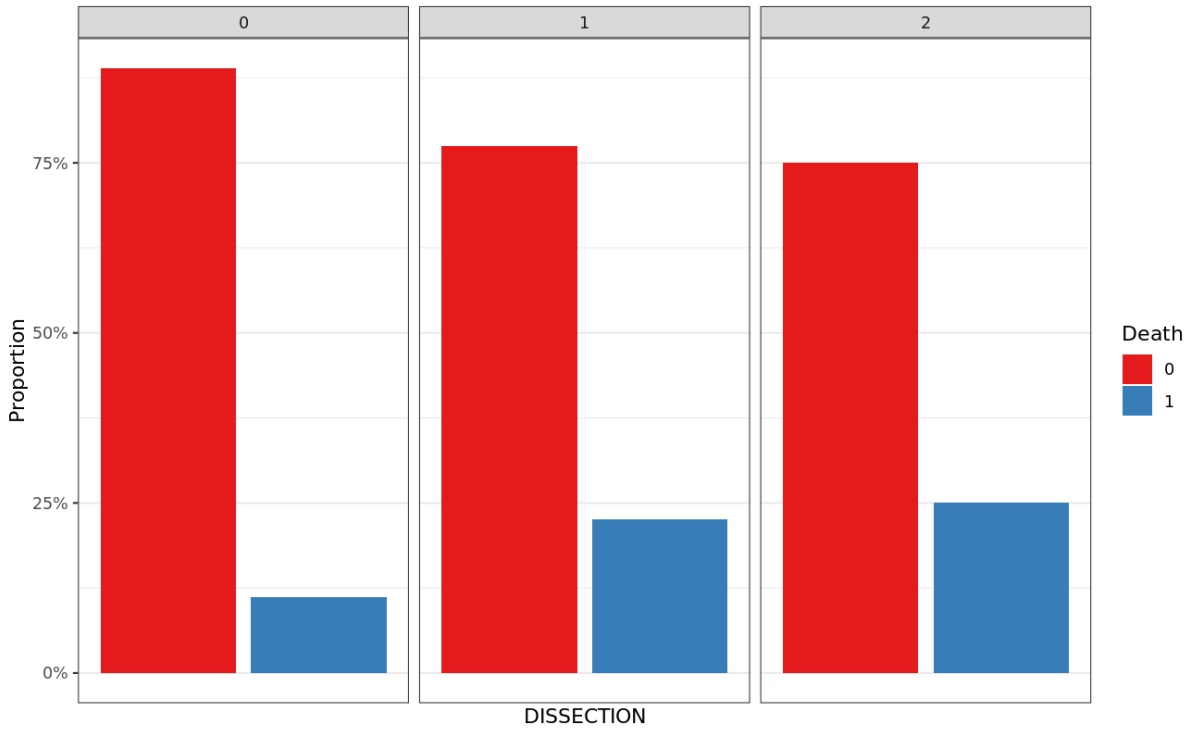
The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

Description of the variable Death

Distribution of Death by class



	0[NO DISSECTION]	1[DISSECTION]
Death	43 (81%)	10 (19%)



	DISSECTION 0 (n = 18)	DISSECTION 1 (n = 31)	DISSECTION 2 (n = 4)	n	p
Death, n					
0[NO]	16 (89%)	24 (77%)	3 (75%)	43	0.55
1[YES]	2 (11%)	7 (23%)	1 (25%)	10	-

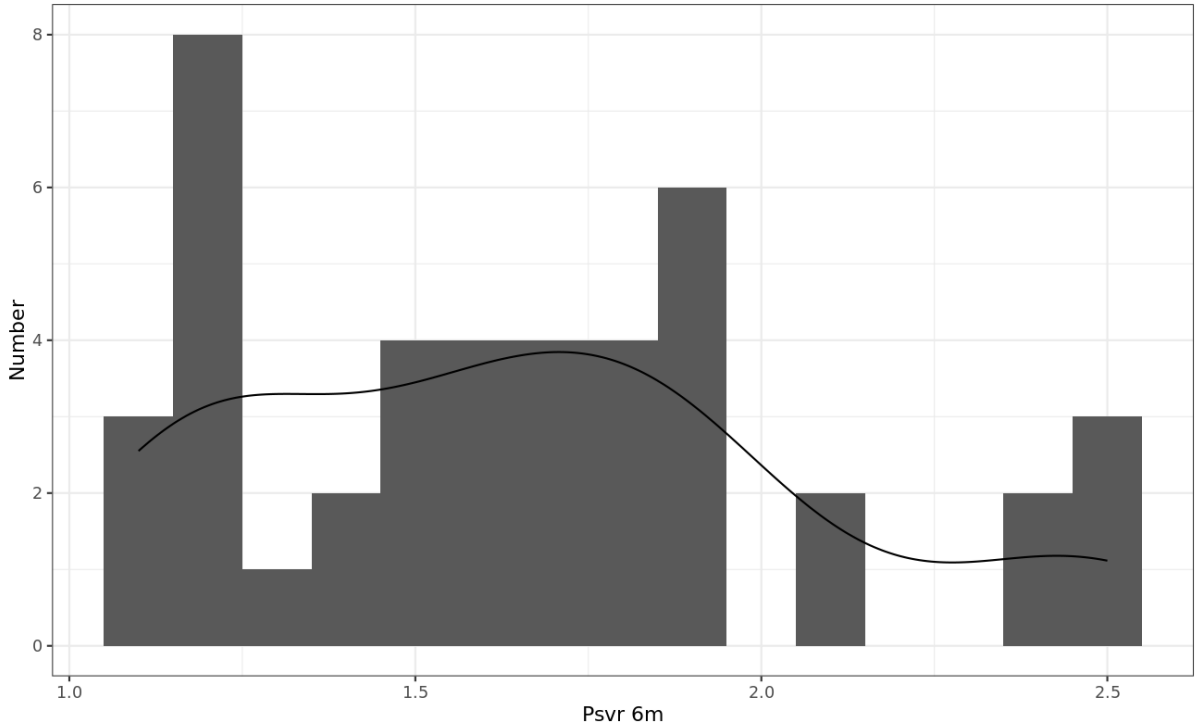
Interpretation

The distribution of Death is not significantly different depending on DISSECTION (p = 0.55).

The Conditions for applying the Chi2 test not being met (at least one of the cells in the contingency table has too few theoretical observations), an exact Fisher test was performed.

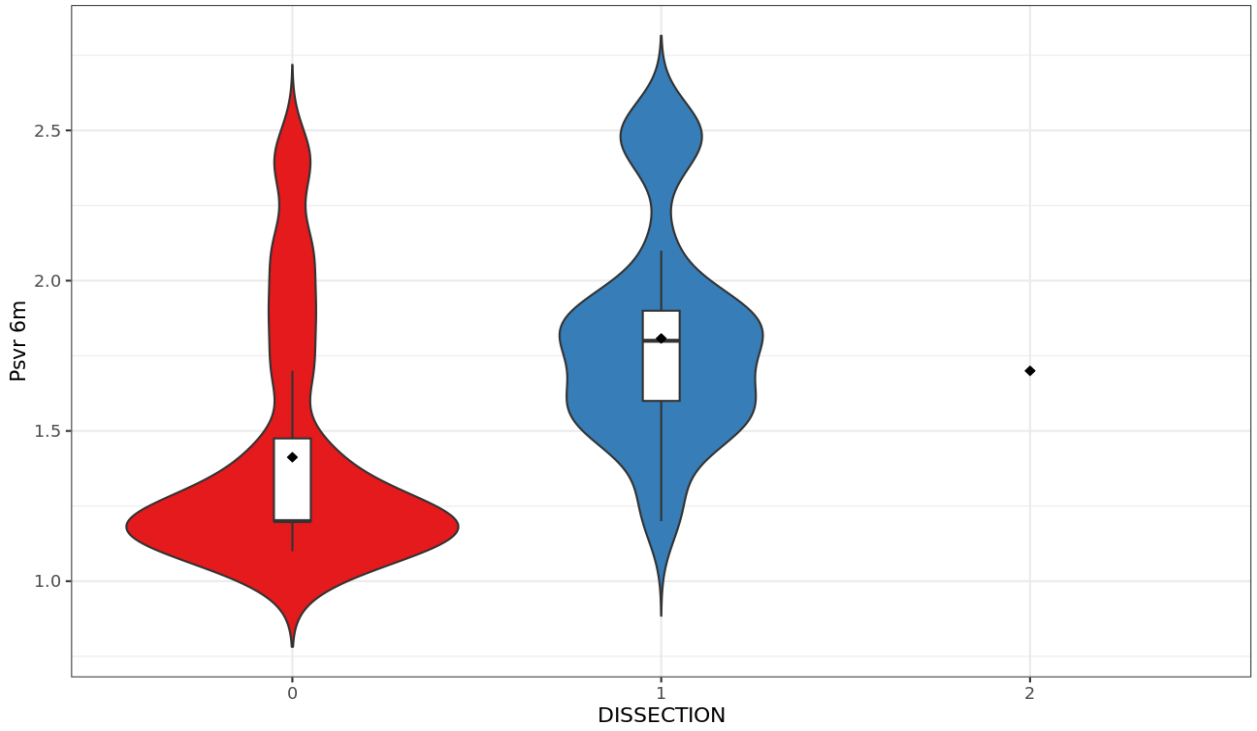
Description of the PSVR[Peak systolic velocity ratio at 6th month

PSVR 6m distribution



	mean (SD)	median [Q25-75]	min	max	n
Psvr 6m	1.66 (0.410)	1.60 [1.25; 1.90]	1.10	2.50	43

Description of the distribution of PSVR at 6m depending on DISSECTION



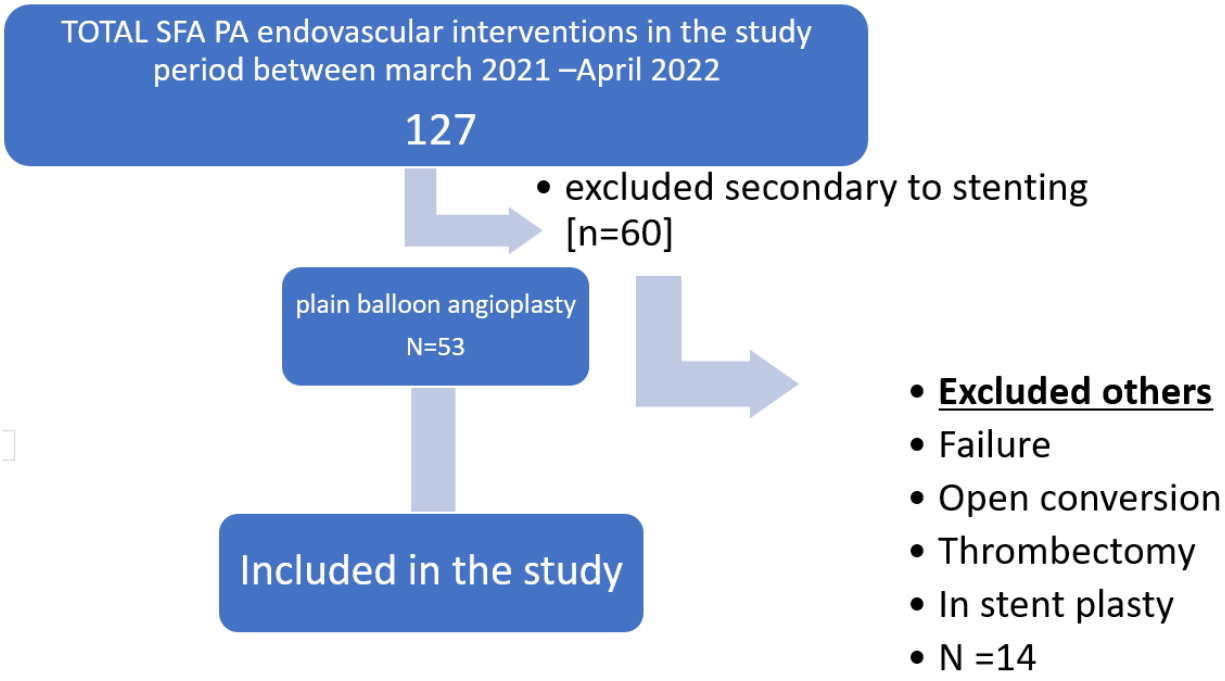
	DISSECTION 0 (n = 16)	DISSECTION 1 (n = 26)	DISSECTION 2 (n = 1)	n	p
PSVR 6m, median [Q25-75]	1.20 [1.20; 1.47]	1.80 [1.60; 1.90]	1.70 [1.70; 1.70]	43	**<0.01**

Interpretation

As the numbers of subjects compared were small, a non-parametric test was carried out (Kruskal-Wallis test). The exact interpretation is that the average rank of Psvr 6m is significantly different depending on DISSECTION (p = <**0.01**).

Discussion :

Flowchart of the study



Among the demographic factors, age, sex, comorbid status, hba1c, and lipid profile were not found to be associated with the severity of dissection.

The main findings of this study are that the PSVR in the mild angiographic dissection group was similar to that in the moderate dissection group.

The PSVR in the mild and moderate angiographic dissection groups was significantly worse compared with that in the no dissection group, which is in correlation with a study done by Norihiro Kobayashi et al. [30].

The distribution of above-ankle amputation is significantly different depending on the type of dissection ($p = 0.035$), with a higher number of amputations with an increasing grade of dissection. The distribution of deaths is not significantly different depending on the type of dissection ($p = 0.55$).

The distribution of the post-6m WIFI stage is significantly different depending on the type of dissection (p = < 0.01), with a greater number of patients in stage 4 in the type 2 dissection group. Our study showed that the reference vessel diameter was not significantly related to dissection severity, which contrasts with the study by Hiramori S et al [31]

The distribution of balloon diameter, length, inflation time, and inflation pressure were not significantly different depending on the type of dissection (p >0.05).

The distribution of the treated segment of SFA PA, reference vessel diameter, number of outflow vessels, FP/IP grade, and GLASS stage was not significantly different depending on the type of dissection (p >0.05). Fujihara et al. [13] reported that severe dissection (type C or higher) was detected in 42% of patients who underwent balloon angioplasty; independent predictors were a reference vessel diameter of 5.0 mm and total occlusion [33]

Limitations.

First, this was an institution based open study, and uncontrolled confounding factors could have contributed to these findings.

second, we considered the FP segment as a single vessel and focused on investigating the relationship between the dissection type and endovascular, morphological and clinical outcomes. Therefore, we did not differentiate between the superficial femoral, and popliteal arteries. Further studies regarding the impact of the FP segment location are necessary.

Thirdly less sample size might have influenced the results. In particular, selection bias regarding balloon profiles, inflation times could not be ruled out.

CONCLUSION:

- There is a significant difference in PSVR , WIFI stage at 6th month follow up & above ankle amputation in patients of femoropopliteal non flow limiting dissection based on simple classification for angiographic dissection, with higher PSVR ,WIFI stage, above ankle amputation with increasing grade of dissection.
- There are no significant predicting factors for different types of femoropopliteal dissection in my study
- Balloon inflation time and balloon lengths had no effect on the type of angiographic dissection in femoropopliteal segment
- We recommend based on our study ,to consider ancillary treatment options like stenting or DCB following type 2 dissection as per the simple classification to improve the hemodynamic outcome.

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ANNEXURE - 1

STUDY PROFORMA:

DEMOGRAPHIC DATA
NAME :
ADDRESS :
AGE/SEX :
HOSPITAL No. :
TELEPHONE :
DATE OF ADMISSION :

A. ***Baseline characteristics of the patients***

1. sex M/ F
2. Age[YEARS]
3. Hypertension YES/NO
4. Dyslipidaemia YES/NO
5. Diabetes mellitus YES/NO
6. CKD YES/NO
7. Haemodialysis YES/NO
8. Current smoking YES/NO
9. Prior coronary artery disease YES/NO
10. Prior cerebrovascular disease YES/NO
11. SVS WIFI classification [STAGE]

B. ***LAB PARAMETERS:***

1. *HbA1C,FLP*
2. Preprocedural ABI, mm Hg [HEMODYNAMIC PARAMETER]

C. ***Lesion characteristics***

1. Lesion length, mm

2. SITE OF LESION IN FEMOROPOLITEAL: GLASS

a) PROXIMAL/MID/DISTAL SFA

b) P1, P2, P3

3. OUTFLOW LESION: DISTAL runoff: 1/2/3

4. Reference vessel diameter, mm

D. ***Interventional results***

1. Number of balloons
2. Balloon diameter, mm
3. Balloon length, mm
4. Inflation time, seconds

E. ***OUTCOMES:*** [6TH MONTH]

WIfI stage [CLINICAL SUCCESS]

PSVR [HEMODYNAMIC SUCCESS]

ANNEXURE - 2

PATIENT CONSENT FORM

TITLE: ***Predicting factors & clinical outcomes of FEMORPOPLITEAL angiographic dissection following balloon angioplasty:*** **an Institutional based prospective study**

I have been explained about the nature of the study. I have been explained that the study identifies ***Predicting factors & clinical outcomes of FEMORPOPLITEAL angiographic dissection following balloon angioplasty***

I have been read to about and understand the purpose of the study, type of study, risk and benefits associated with my involvement. I have been given the opportunity to ask questions regarding various aspects of the study. I understand that confidentiality is maintained in patient details. The information collected is only for research. I also understand that I am free to withdraw from the study at any point of time and standard of care provided to me does not change if I am quitting/not willing to take part in the study.

I the undersigned agree to voluntarily participate in this study and authorize the collection and disclosure of my personal information for the purpose of research.

- **Subject name and signature/ thumb impression: Date:**
- **Name and signature/ thumb impression of witness: Date:**
- **Name and signature of person obtaining consent: Date:**

ANNEXURE - 3
PATIENT INFORMATION SHEET

1. What is the background to and purpose of the study?
   The purpose of the study is to Predicting factors & clinical outcomes of Femoropopliteal angiographic dissection following balloon angioplasty: An Institutional based prospective study

2. Do I have to take part?
   Yes, it is necessary for you to actively participate in the study as your regular follow up and strict adherence to the given instructions is necessary for a comprehensive analysis of result.

3. What will happen to me if I take part?
   Your treatment or plan of intervention and further follow up and care will, in no way, be affected.

4. What do I have to do?
   You will be given a set of instructions regarding medications, follow-up visits, follow-up PVRs & doppler, wound care etc. which you have to follow scrupulously. These instructions are in accordance to the standard protocol of patient-care at our institute. You also have to notify us when you have any worsening of symptoms or deterioration of wound status (if any).

5. What are the possible side effects, risks and discomforts of taking part?
   No additional intervention or extra tests are being performed on you. Hence, participation in this study has no possible side-effects, risks or discomforts.

6. What are the possible benefits of taking part?
   NA

7. How will my personal data be used?
   Your personal data will be used only for the purpose of study and strict confidentiality will be maintained about the same.

8. Will there be provision for free treatment for research related injury?
   There is no possible research related injury, hence, no compensation is necessary.

9. Will compensation be paid to the subjects if disability or death results from such study?
   As there is no change in standard of patient care or intervention, there is no possibility of study related disability or death.

10. Whom should I contact if I need more information or help?
    You can contact me i.e. Dr.Siddharth, for further information or help.

Contact Details:

Dr. Siddharth M

Mobile No: 9746553250

NAME OF GUIDE: **Dr. Sumanth Raj KB**

Department of Vascular and
Endovascular surgery Bhagwan
Mahaveer Jain Hospital, Bangalore
Mobile No: 984513711

Dr.M.D Marker
Member Secretary
Ethical Committee of Bhagwan Mahaveer Jain
Hospital, Bangalore Mobile No: 9845081000

The details of the treatment will be recorded by me for research purpose. This research work will only be observational and will not interfere with the treatment course or procedure and

will not cause any risk to your health or extra expenditure. Secrecy will be maintained regarding the nature of your disease and the treatment you will be undergoing and your identity will not be disclosed.

ANNEXURE-4

INFORMED CONSENT FORM:

Study title: Predicting factors & clinical outcomes of Femoropopliteal angiographic dissection following balloon angioplasty: An Institutional based prospective study

Study site: Bhagwan Mahaveer Jain Hospital, Bangalore.

I have been explained about the nature of the study. I have read about and understand the purpose of the study, type of study, risk and benefits associated with my involvement. I have been given the opportunity to ask questions regarding various aspects of the study. I understand that confidentiality is maintained in patient details. The information collected is only for research. I also understand that I am free to withdraw from the study at any point of time and standard of care provided to me does not change if I am quitting to take part in the study.

I the undersigned agree to voluntarily participate in this study and authorize the collection and disclosure of my personal information for the purpose of research.

		SUBJECT INITIAL BOX
1	The content of the above consent form and the procedure has been explained to me in a language ---------- known to me and I have understood the same.	
2	I understood that my participation in the study is voluntary and that I am free to withdraw any time, without my medical care or legal rights being affected.	
3	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose (s).	
4	I agree to take part in the above study.	
5	I have received a copy of the signed and dated informed Consent Form.	

Subject name and signature/ thumb impression: **Date:**

Name and signature/ thumb impression of witness: **Date:**

Name and signature of person obtaining consent: **Date**

Doctors name and signature: **Date:**

ANNEXURE-5

SCIENTIFIC COMMITTEE APPROVAL LETTER:

Bhagwan Mahaveer
JAIN HOSPITAL
A Unit of Bhagwan Mahaveer Memorial Jain Trust
080 4087 5555 | 4110 0550
No. 17, Millers Road, Vasanthnagar
Bengaluru 560052
website - www.bmjh.org

BMJH
Caring with Compassion

caring
with
compassion

SCIENTIFIC COMMITTEE

APPROVAL CERTIFICATE OF DISSERTATION FOR NBE

Approval has been granted by Scientific Committee of Bhagwan Mahaveer Jain Hospital for the following Dissertation as per NBE requirement **PREDICTING FACTORS & CLINICAL OUTCOMES OF FEMORPOPLITEAL ANGIOGRAPHIC DISSECTION FOLLOWING BALLOON ANGIOPLASTY** Conducted by **DR. SIDDHARTH.M** Department of **VASCULAR SURGERY** under the guidance of **DR. SUMANTH RAJ** approximate period of study is from **JUNE 2021 to MAY 2022.**

Scientific Committee meeting held on **8/06/2021.**

Date : 22/07/2021

Dr. (Wg Cdr) M.D.Marker
Medical Director
BMJH Scientific Committee

Dr. (Wg Cdr) M.D. Marker
Medical Director
BHAGWAN MAHAVEER JAIN HOSPITAL
Bangalore-560 052

ANNEXURE-6

ETHICAL COMMITTEE APPROVAL LETTER:

ETHICS COMMITTEE ON HUMAN RESEARCH
BHAGWAN MAHAVEER JAIN HOSPITAL
A UNIT OF BHAGWAN MAHAVEER MEMORIAL JAIN TRUST
Millers Road, Vasanthnagar, Bangalore - 560 052.
✆ : 4087 5555 (30 Lines), 4110 0550, Fax: 080 2226 1153
e-mail : bmjh.mdoffice@gmail.com

APPROVAL CERTIFICATE OF DISSERTATION FOR NBE

Approval has been granted by Ethics Committee of Bhagwan Mahaveer Jain Hospital for the following Dissertation as per NBE requirement **PREDICTING FACTORS & CLINICAL OUTCOMES OF FEMORPOPLITEAL ANGIOGRAPHIC DISSECTION FOLLOWING BALLOON ANGIOPLASTY** Conducted by **DR. SIDDHARTH M** Department of **VASCULAR SURGERY** under the guidance of **DR. SUMANTH RAJ** approximate period of study is from **JUNE 2021 to MAY 2022.**

Ethics Committee meeting held on **8/06/2021.**

Date : 22/07/2021

Dr. (Wg Cdr) M.D.Marker
Member Secretary
BMJH Ethics Committee
Member Secretery on
Ethics Committee on Human Research
Bhagwan Mahaveer Jain Hospital
Miller's Road, Vasanthnagar
Bangalore-560 052

ANNEXURE-7

MASTER CHART

PT									DIALYSIS										GLASS	SFA PROX	SFA MID	SFA DISTAL	P1	P2	P3	CTO		DISSECTION	RVD	NUMBER OF SEGMENTS	BALLOON DIAMETER	BALLOON LENGTH	TOTAL INFLATION							
1	82	F	12	YES	YES	NO	NO	NO	NO	0.8	NO	YES	176	162	54	42	1	3	2	0	1	0	0	0	0	YES	2	0	4	1	4	80	180	4	1	1	1	1.2	0	0
2	70	M	9.5	YES	YES	NO	NO	YES	NO	1.3	NO	NO	140	257	78	49	3	3	3	0	0	0	0	1	0	NO	3	0	4.5	1	4	60	120	4	3	2	2	1.7	0	0
3	76	M	9.1	YES	YES	NO	NO	YES	NO	1.6	NO	NO	215	231	89	45	3	4	3	0	1	1	0	1	0	NO	1	0	4.5	2	5	150	120	4	4	2	2	2.1	0	0
4	68	F	7.9	YES	YES	YES	NO	YES	NO	0.8	YES	NO	175	184	75	42	3	3	3	0	0	0	0	1	0	NO	1	0	5	1	4	60	120	4	3	3	3	1.1	0	0
5	55	M	7	YES	NO	NO	NO	NO	NO	0.8	NO	NO	176	161	80	39	4	3	3	0	0	0	0	1	0	NO	2	0	4.5	1	4	60	120	4	4	2	2	1.4	0	0
6	34	M	8.2	YES	NO	NO	NO	NO	NO	1.7	NO	NO	189	164	51	49	3	3	3	0	1	1	1	0	0	NO	2	0	5	2	5	200	180	4					1	1
7	70	M	9.5	YES	YES	NO	NO	NO	NO	1.7	NO	NO	140	257	78	49	3	3	3	0	0	0	0	1	0	NO	3	0	4.5	1	4	60	120	4	3	3	3	1.9	0	0
8	83	F	12	YES	YES	NO	NO	NO	NO	1.7	NO	YES	195	188	78	41	3	3	3	1	1	1	0	1	0	NO	3	0	5	2	5	200	120	4		1	1	2.4	0	0
9	82	M	5.8	YES	NO	YES	YES	NO	NO	0.9	YES	NO	146	182	93	45	4	4	3	1	1	1	0	1	1	NO	1	0	4.5	2	5	200	120	4	4	1	1	1.2	0	0
10	57	M	7.9	YES	YES	NO	NO	NO	NO	0.9	NO	NO	203	188	83	38	1	4	2	0	1	1	0	0	0	NO	1	0	5	1	5	150	120	4	2	1	1	1.2	0	0
11	76	F	9.1	YES	YES	NO	NO	YES	NO	1.6	NO	NO	215	231	89	45	3	4	3	0	1	1	0	1	0	NO	1	0	4.5	2	5	150	120	4	3	1	1	1.2	0	0
12	65	M	9.3	YES	YES	NO	YES	YES	NO	1.3	NO	NO	200	189	102	38	3	4	3	1	1	1	0	1	1	YES	2	0	5	2	5	200	120	3		1	1	1.2	0	0
13	62	M	10	YES	NO	YES	YES	NO	NO	1.2	YES	NO	168	256	53	46	3	3	3	0	0	0	0	1	0	NO	1	0	5	1	4	60	120	4	3	3	3	1.2	0	0
14	55	M	7	YES	NO	NO	NO	NO	NO	0.8	NO	NO	176	161	80	39	4	3	3	0	0	0	0	1	0	YES	2	0	4.5	1	4	60	120	4					1	1
15	81	M	6.9	YES	YES	NO	NO	NO	NO	0.9	NO	NO	155	226	82	48	4	4	3	0	0	1	1	0	0	YES	1	0	5	1	5	150	120	3	1	1	1	1.1	0	0
16	62	M	8.9	YES	YES	YES	NO	YES	YES	4.9	YES	YES	148	133	111	50	1	3	2	0	1	0	0	0	0	YES	2	0	4.5	1	5	60	120	3		2	2	1.1	0	0
17	68	M	7.9	YES	YES	YES	NO	NO	NO	0.8	YES	NO	175	184	75	42	3	3	3	0	0	0	0	1	0	NO	1	1	5	1	4	60	120	4	2	2	2	1.8	0	0
18	55	M	7	YES	NO	NO	NO	NO	NO	0.8	NO	NO	176	161	80	39	4	3	3	0	0	0	0	1	0	YES	2	1	4.5	1	4	60	120	4	3	2	2	1.9	0	0
19	81	M	6.9	NO	YES	NO	NO	NO	NO	0.9	NO	NO	155	226	82	48	4	4	3	0	0	1	1	0	0	YES	1	1	5	1	5	150	120	3		1	1	1.5	0	0
20	71	F	7.9	NO	YES	NO	NO	NO	NO	0.8	NO	NO	159	129	114	43	3	3	3	0	0	1	0	1	0	YES	3	1	5	2	5	150	120	4	4	4	4	2.5	1	0
21	78	F	9	YES	YES	YES	NO	NO	NO	1	YES	YES	167	194	57	37	4	3	3	0	0	1	0	1	0	YES	3	1	4.5	2	5	150	120	4					1	1
22	66	M	12	YES	YES	NO	NO	NO	NO	1.2	NO	NO	200	147	103	49	3	3	3	0	0	0	0	0	1	NO	3	1	5	1	4	60	120	3	2	2	2	2.5	0	0
23	74	M	8.9	YES	YES	NO	NO	NO	YES	3	NO	NO	196	266	52	35	2	3	2	1	0	1	0	0	0	YES	2	1	4.5	1	5	200	180	4	4	4	4	1.8	0	0
24	70	M	6.6	NO	YES	NO	NO	NO	NO	0.8	NO	NO	191	243	48	48	2	4	3	0	1	1	0	0	0	NO	1	1	4.5	1	5	200	180	4	3	2	2	1.9	0	0
25	34	M	8.2	YES	NO	NO	NO	YES	NO	1.2	NO	NO	189	164	51	49	3	3	3	0	1	1	1	0	0	NO	2	1	5	2	5	200	180	4	4	4	4	1.6	0	0
26	83	F	12	YES	YES	NO	NO	YES	NO	1.2	NO	YES	195	188	78	41	3	3	3	1	1	1	0	1	0	NO	3	1	5	2	5	200	120	4		2	2	1.8	1	0
27	82	M	5.8	NO	NO	YES	YES	NO	NO	0.9	YES	NO	146	182	93	45	4	4	3	1	1	1	0	1	1	YES	1	1	4.5	2	5	200	120	4	4	2	2	1.5	0	0
28	57	M	7.9	YES	YES	NO	NO	NO	NO	0.9	NO	NO	203	188	83	38	1	4	2	0	1	1	0	0	0	NO	1	1	5	1	5	150	120	4	3	3	3	1.9	0	0
29	65	M	9.3	YES	YES	NO	YES	YES	NO	1.3	NO	NO	200	189	102	38	3	4	3	1	1	1	0	1	1	NO	2	1	5	2	5	200	120	3	2	2	2	1.7	0	0
30	62	M	10	YES	NO	YES	YES	NO	NO	1.2	YES	NO	168	256	53	46	3	3	3	0	0	0	0	1	0	NO	1	1	5	1	4	60	120	4	4	2	2	1.6	0	0
31	82	M	12	YES	YES	NO	NO	NO	NO	0.8	NO	YES	176	162	54	42	1	3	2	0	1	0	0	0	0	YES	2	1	4	1	4	80	180	4					0	1
32	81	M	6.9	YES	YES	NO	NO	NO	NO	0.9	NO	NO	155	226	82	48	4	4	3	0	0	1	1	0	0	YES	1	1	5	1	5	150	120	3	2	2	2	1.2	0	0
33	62	M	8.9	YES	YES	YES	NO	YES	NO	4.9	YES	YES	148	133	111	50	1	3	2	0	1	0	0	0	0	YES	2	1	4.5	1	4	60	120	3	2	2	2	1.3	0	0
34	71	F	7.9	NO	YES	NO	NO	NO	NO	0.8	NO	NO	159	129	114	43	3	3	3	0	0	1	0	1	0	YES	3	1	5	2	5	150	120	4		2	2	1.7	0	0
35	66	F	12	YES	YES	NO	NO	NO	NO	1.2	NO	NO	200	147	103	49	3	3	3	0	0	0	0	0	1	NO	3	1	5	1	4	60	120	3	1	2	2	2.4	1	0
36	74	M	8.9	YES	YES	NO	NO	YES	NO	1.1	NO	NO	196	266	52	35	2	3	2	1	0	1	0	0	0	YES	2	1	4.5	1	5	200	180	4	3	2	2	2.1	0	0
37	70	M	6.6	YES	YES	NO	NO	NO	NO	0.8	NO	NO	191	243	48	48	2	4	3	0	1	1	0	0	0	NO	1	1	4.5	1	5	200	180	4	3	2	2	1.9	0	0
38	56	M	9	YES	YES	YES	NO	NO	NO	1	YES	YES	167	194	57	37	4	3	3	0	0	1	0	1	0	YES	3	1	4.5	2	5	150	120	4	3	1	1	2.5	0	0
39	62	M	8.9	YES	YES	YES	NO	YES	YES	4.9	YES	YES	148	133	111	50	1	3	2	0	1	0	0	0	0	YES	2	2	4.5	1	4	60	120	3					1	1
40	62	M	9.7	YES	YES	NO	YES	YES	NO	0.8	YES	YES	188	228	84	46	2	3	2	0	1	1	0	0	0	NO	3	2	4	1	4	200	180	4					0	1
41	83	F	9	YES	YES	YES	NO	NO	NO	1	YES	YES	167	194	57	37	4	3	3	0	0	1	0	1	0	YES	3	2	4.5	2	5	150	120	4	3	3	3	1.7	0	0
42	62	F	9.7	YES	YES	NO	YES	YES	NO	0.8	NO	YES	188	228	84	46	2	3	2	0	1	1	0	0	0	NO	3	2	5	1	5	200	180	4					0	1
43	82	F	12	YES	YES	NO	NO	NO	NO	0.8	NO	YES	176	162	54	42	1	3	2	0	1	0	0	0	0	YES	2	0	4	1	4	80	180	4	1	1	1	1.2	0	0
44	55	M	7	YES	NO	NO	NO	NO	NO	0.8	NO	NO	176	161	80	39	4	3	3	0	0	0	0	1	0	NO	2	0	4.5	1	4	60	120	4	4	2	2	1.4	0	0
45	78	F	9	YES	YES	YES	NO	NO	NO	1	YES	YES	167	194	57	37	4	3	3	0	0	1	0	1	0	YES	3	1	4.5	2	5	150	120	4					1	1
46	57	M	7.9	YES	YES	NO	NO	NO	NO	0.9	NO	NO	203	188	83	38	1	4	2	0	1	1	0	0	0	NO	1	1	5	1	5	150	120	4	3	3	3	1.9	0	0
47	34	M	8.2	YES	NO	NO	NO	YES	NO	1.2	NO	NO	189	164	51	49	3	3	3	0	1	1	1	0	0	NO	2	1	5	2	5	200	180	4	4	4	4	1.6	0	0
48	82	M	12	YES	YES	NO	NO	NO	NO	0.8	NO	YES	176	162	54	42	1	3	2	0	1	0	0	0	0	YES	2	1	4	1	4	80	180	4					0	1
49	78	F	9	YES	YES	YES	NO	NO	NO	1	YES	YES	167	194	57	37	4	3	3	0	0	1	0	1	0	YES	3	1	4.5	2	5	150	120	4					1	1
50	81	M	6.9	NO	YES	NO	NO	NO	NO	0.9	NO	NO	155	226	82	48	4	4	3	0	0	1	1	0	0	YES	1	1	5	1	5	150	120	3		1	1	1.5	0	0
51	34	M	8.2	YES	NO	NO	NO	YES	NO	1.2	NO	NO	189	164	51	49	3	3	3	0	1	1	1	0	0	NO	2	1	5	2	5	200	180	4	4	4	4	1.6	0	0
52	83	F	12	YES	YES	NO	NO	YES	NO	1.2	NO	YES	195	188	78	41	3	3	3	1	1	1	0	1	0	NO	3	1	5	2	5	200	120	4		2	2	1.8	1	0
53	82	M	5.8	NO	NO	YES	YES	NO	NO	0.9	YES	NO	146	182	93	45	4	4	3	1	1	1	0	1	1	YES	1	1	4.5	2	5	200	120	4	4	2	2	1.5	0	0